बायोटेकनोलॉजी विभाग
DEPARTMENT OF BIOTECHNOLOGY

nbm
NATIONAL BIOPHARMA MISSION
innovate in India for inclusiveness (i3)

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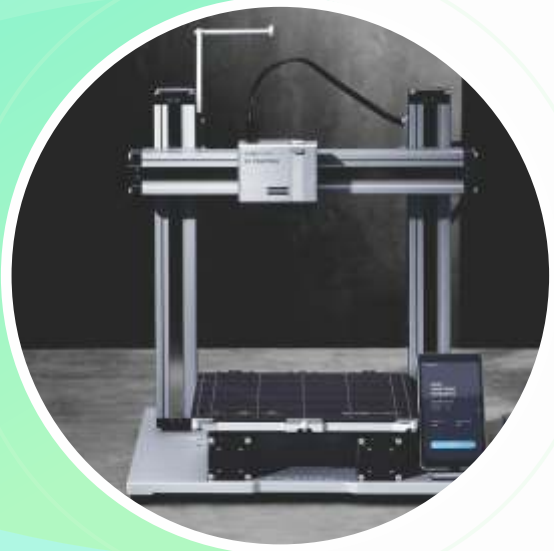
birac
Ignite Innovate Incubate

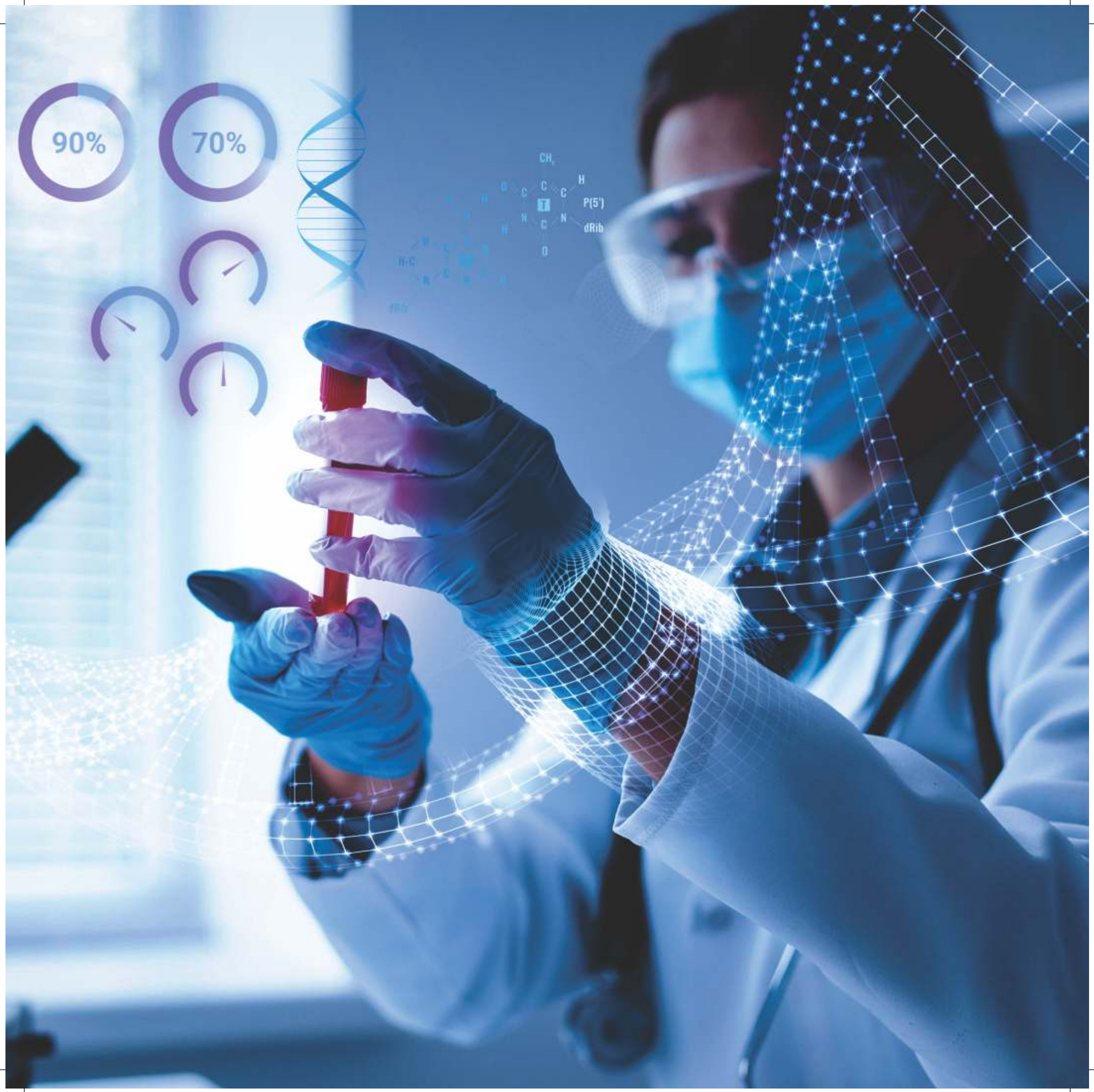
THE WORLD BANK



NATIONAL BIOPHARMA MISSION

'CATALYZING TRANSFORMATIVE IMPACT ON AFFORDABLE PRODUCT DEVELOPMENT IN INDIA'

IMPACT REPORT 2024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Cabinet approved Program of the
Department of Biotechnology

NATIONAL BIOPHARMA MISSION

Industry-Academia Collaborative Mission For Accelerating Discovery Research To Early Development For Biopharmaceuticals - *"Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation"*

Implemented by Biotechnology Industry Research Assistance Council

Funded by GoI with (50% cost sharing through World Bank Loan).

CONTENTS

Dr. Jitendra Singh
Hon'ble Minister of State (IC)
Ministry of Science & Technology, and Ministry of Earth Sciences; Minister of State, PMO; Ministry of Personnel, Public Grievance & Pensions; Department of Atomic Energy; and Department of Space, Govt. of India

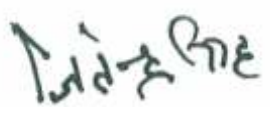
Message from Dr. Jitendra Singh

It is my pleasure to present this comprehensive book showcasing the transformative journey of the National Biopharma Mission, a Cabinet approved Mission of the Department of Biotechnology, driving health innovation in India. This initiative stands as a symbol of Government's commitment to harness biopharmaceutical innovation for national growth and global impact.

The National Biopharma Mission has been pivotal in fostering an ecosystem conducive to innovation, collaboration, and economic advancement through strategic investments, cutting-edge research initiatives, and industry-academic partnerships. This has facilitated the development of affordable healthcare solutions, talent development and building skill & capacities in the country. This Mission serves well towards the clarion call of our Honourable Prime Minister for an Aatmanirbhar Bharat.

As we chart our future course, it is imperative to build upon our achievements and address emerging challenges. Future strategy in the area must align with our vision to establish India as a global leader in biopharmaceutical research, development and manufacturing. Future efforts will not only sustain our momentum but also solidify India's position as a formidable player on the global biopharmaceutical stage.

With deep appreciation for the collective efforts of all stakeholders involved, I extend my warmest felicitation to the NBM, BIRAC and DBT teams for their unwavering commitment, and relentless pursuit of excellence in steering this Mission. This book reflects not only the milestones achieved but also the impact that it has created in Biopharma innovation ecosystem.



Dr. Jitendra Singh
Union Minister of State (Independent Charge) for Science and Technology, Minister of State (Independent Charge) for Earth Sciences, MoS PMO, Department of Atomic Energy, Department of Space, Personnel, Public Grievances and Pensions

Dr. Rajesh S. Gokhale
Secretary, Department of Biotechnology, Director General, BRIC and Chairperson BIRAC

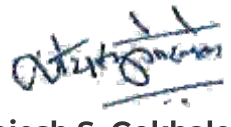
Message from Dr Rajesh S. Gokhale

I am delighted to present to you the Impact Book of the National Biopharma Mission, an endeavour of the Department of Biotechnology, Government of India, implemented by BIRAC. This book serves as a testament to the remarkable journey and transformative impact National Biopharma Mission has had on the landscape of healthcare innovation ecosystem in India.

Through this document, you will discover a compilation of achievements spanning the realms of vaccine development, biotherapeutics, biosimilars, medical devices and diagnostics. Through relentless dedication and strategic deployment of funds, the mission has fostered an environment conducive to cutting-edge research and development, driving India to the forefront of global biopharmaceutical innovation.

Central to the Mission's success is its unwavering commitment to strengthening ecosystem for affordable product development in the country. From the establishment of clinical trial networks across four critical indications to setting-up of the nationwide network of technology transfer offices, supporting the setting up of shared facilities to support development of vaccine, biotherapeutics, medical devices and diagnostics, the Mission has laid the groundwork for sustainable growth and collaboration within the biopharma sector. Moreover, its support for multi-institutional translational research consortiums underscores a collaborative approach to tackling complex healthcare challenges. This has not only catalysed growth in the Biopharma sector but has also saved cost and time in the development of newer products.

As we reflect on the achievements recorded within this Impact Book, I extend heartfelt acknowledgment to all stakeholders who have contributed to the success of the National Biopharma Mission. The journey traversed thus far, driving innovation, collaboration, and impact needs to be shared and applauded. It also needs to be deliberated to script an even greater and significant voyage for realizing the goals of the Vikasit Bharat.



(Dr. Rajesh S. Gokhale)
SECRETARY
Government Of India
Ministry Of Science & Technology Department Of Biotechnology
Block-2, Floor, CGO Complex, Lodhi Road, New Delhi-110003

Dr. Alka Sharma
Senior Adviser/Scientist H, DBT
and Former MD, BIRAC

Message from Dr. Alka Sharma

It is with great pride and profound gratitude that I present this Impact book, commemorating the achievements of the National Biopharma Mission. The National Biopharma Mission was conceived not merely as a program, but as a visionary endeavour to propel India into a leadership role in biopharmaceuticals. From its inception, the Mission set out to foster an ecosystem conducive to rapid and efficient product development, nurturing innovation and collaboration across academia, industry, and the Government.

The journey of this Mission has been punctuated by numerous milestones, each marking a significant stride towards our overarching goal. However, perhaps the most profound testament to its impact came during the unprecedented challenge of the COVID-19 pandemic. While the world retreated indoors, the National Biopharma Mission surged forward, channelling its resources and expertise into combating the pandemic. We rallied behind projects aimed at developing novel vaccines, biotherapeutics, and diagnostic kits, while also bolstering domestic manufacturing capabilities to meet the urgent demands of the hour.

The success of the National Biopharma Mission stands as a testament to the dedication and collective efforts of countless individuals and organizations who embraced its vision. Together, we have not only strengthened our capabilities in biopharmaceutical research and development but have also laid a sturdy foundation for a thriving bioeconomy.

As we celebrate these achievements, it is imperative that we look ahead with a renewed sense of purpose and ambition. The lessons learnt and milestones achieved during this Mission serve as a launchpad for our next endeavour—a larger, more ambitious Mission aimed at further catalysing our national bioeconomy and reinforcing India's position as a global leader in biopharmaceutical innovation.

I extend my heartfelt appreciation to everyone who has contributed to the success of the National Biopharma Mission. Their dedication, ingenuity, and passion have made this journey possible, and together, we will continue to chart new frontiers in the realm of biopharmaceuticals.

Dr. Alka Sharma
Government of India
Ministry of Science & Technology
Department Of Biotechnology
Block-2, (6th-8th Floor) CGO Complex, Lodhi Road, New Delhi-110003

Dr Jitendra Kumar
Managing Director,
Biotechnology Industry Research Assistance Council (BIRAC)

Message from Dr Jitendra Kumar

As the Managing Director of BIRAC, it is with immense pride and gratitude that I share this message. Over the past 12 years, BIRAC has been a beacon of innovation in the biotechnology ecosystem, catalysing transformative growth stories that have propelled India onto the global stage.

In the midst of India's rapid economic ascent, BIRAC stands ready to shoulder the responsibility of driving innovation and fostering sustainable growth. It is with this vision in mind that we are honoured to drive the National Biopharma Mission, a pivotal initiative spearheaded by the Department of Biotechnology, Government of India, and co-funded by the World Bank.

The National Biopharma Mission represents a watershed moment in India's biopharmaceutical landscape, driving transformative changes that are revolutionizing healthcare delivery. From the development of vaccines, biotherapeutics, to medical devices and diagnostics, the mission is not only addressing critical healthcare needs but also driving India to be a leading global player in biopharmaceutical innovation.

Moreover, the mission's steadfast commitment to ecosystem development is evident in its support for clinical trial networks, technology transfer offices, and translational research consortiums. By fostering collaboration and knowledge exchange, the mission is nurturing a vibrant and interconnected biopharmaceutical ecosystem in India.

At the heart of this journey is our unwavering dedication to excellence and impact. Through our collective efforts, we are not only transforming healthcare outcomes but also driving socio-economic development across the nation.

As we celebrate the achievements enshrined in this Impact Book, let us reaffirm our commitment to innovation, collaboration, and inclusivity. Together, we will continue to push the boundaries of possibility and unlock new opportunities for growth and prosperity.

I extend my heartfelt gratitude to all stakeholders who have contributed to the success of the National Biopharma Mission. Your unwavering support and dedication have been instrumental in shaping the future of biopharmaceuticals in India.

Dr Jitendra Kumar
Managing Director,
Biotechnology Industry Research Assistance Council (BIRAC)

Prof. K. Srinath Reddy
Founder (Past) President and
Honorary Distinguished Professor
Public Health Foundation Of India

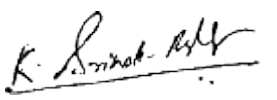
Message from Prof. K. Srinath Reddy

India's role as a major supplier of essential, quality assured vaccines and drugs has been recognized and respected worldwide for several years. That has been further amplified in the context pandemic preparedness and response which is high on global health agenda after Covid-19. The need to extend India's expertise further, into the design, evaluation and manufacture of a wide range of medical devices, is also clear in a global environment where impactful innovation must be matched by affordability.

The National Biopharma Mission (NBM) has provided vision and Vigor to India's efforts to scale up research and development in the area of vaccines, biologicals and devices. It has helped to develop demographic surveillance sites for community-based identification of pathogens. These sites also serve as research locations for community based clinical trials which aim to evaluate the effectiveness and safety of vaccines and therapeutic agents.

NBM has also catalysed or facilitated networks of collaborating research institutions and created a platform for productive public-private partnerships which can advance science for societal benefit. Since its inception, NBM has matched promise with performance and holds the potential to propel Indian biopharma into higher orbits of accomplishment in the design and delivery of valuable products that can protect and promote human health.

As Chair of NBM's Technical Advisory Committee (TAG), it has been a privilege to work with a number of highly accomplished scientists from India and abroad, for providing technical guidance to NBM's secretariat. It has also been a rewarding experience to interact with the many talented scientists and technology innovators who submitted idea-rich proposals seeking support from NBM. The Secretariat of NBM has been outstanding in its meticulous processing of project proposals and progress reports and ably assisted the TAG with well documented reviews and timely updates. I am glad that the National Biopharma Mission conclave will have an excellent opportunity to learn about NBM's exemplary work.



Prof. K. Srinath Reddy
Founder (Past) President and
Honorary Distinguished Professor
Public Health Foundation Of India

From Vision to Reality

Transforming India's Biopharmaceutical Landscape

Dr. Jyoti M. Logani
Scientist F,
Department of Biotechnology
(Nodal Officer - NBM)

Preface

The Department of Biotechnology (DBT) has endeavored over the years to spearhead biotechnology research across India by building coherence between diverse discipline and nurturing an ecosystem for innovation to thrive in the country. In the recent years the industry-academia interface has been strengthened through the Biotechnology Industry Research Assistance Council (BIRAC)– a not-for-profit Public Sector Enterprise of DBT to catalyse translational development.

To catapult the health care innovation ecosystem, the Department supported the implementation of the National Biopharma Mission (NBM), by BIRAC, in alignment with the national missions of Make in India and Start up India. The Mission has been duly approved by the Cabinet at a total cost of Rs. 1500 crore from the Government of India (with 50% of the cost arranged through the World Bank loan).

This Pan-India mission has made catalytic investment for development of nationally critical biopharma and medtech products and has catalyzed directed capacity development investments in areas where ecosystem gaps needed to be bridged in an intensive manner. After 5 years of implementation of this Mission, it is with pride that DBT-BIRAC chronicles the achievement and critical contribution of the “National Biopharma Mission” in the form of an Impact Book. This book serves as a testament to the remarkable strides made in the field of biopharmaceuticals in India.

One of the most significant achievements highlighted in this book include success stories in each of the 3 focus verticals of the mission, i.e. vaccines, biotherapeutics, biosimilars, medical devices, and diagnostics. These advancements are not just technological feats but represent tangible solutions to pressing healthcare challenges. From enhancing vaccine accessibility to expanding the repertoire of biotherapeutics, the National Biopharma Mission has played a pivotal role in improving public health outcomes across the nation, including the significant contribution to fight against the COVID-19 pandemic.

The book sheds light on the ecosystem development efforts facilitated by the mission. By fostering collaboration among academia, industry, and

government agencies, the mission has catalyzed the establishment of clinical trial networks, technology transfer offices, and translational research consortiums. The development of testing facilities underscores the mission's commitment to quality and safety in biopharmaceutical manufacturing. These initiatives are laying the foundation for a vibrant and sustainable biopharmaceutical ecosystem in India, also poised to tackle emerging health issues.

Through this document, we aim to contribute to the discourse surrounding the transformative potential of this Mission and to facilitate informed discussions that can shape the trajectory of biopharmaceutical endeavors in our nation.

On this occasion it is important to extend gratitude to all stakeholders who have contributed to the successful implementation of the National Biopharma Mission. I truly believe that the success of the program is contingent on collaborative efforts involving government bodies, research institutions, industry stakeholders, and the healthcare community at large. I acknowledge the Program Management Unit of NBM- BIRAC which has been instrumental in effective execution of the mission activities. The endeavors of the mission have been strongly backed by oversight from DBT leadership, members of the Inter-ministerial Steering Committee and Advisory Groups comprised of global and national leaders from industry and academia. I also acknowledge the support provided by IAVI India and Sathguru Management Consultants as Technical Knowledge Partner for the National Biopharma Mission.

Dr. Jyoti M. Logani
Scientist F, Department of Biotechnology
(Nodal Officer- NBM)

Dr Raj K Shirumalla
Mission Director, NBM

About The Book

In the dynamic and ever-evolving landscape of healthcare innovation in India, the National Biopharma Mission stands as a beacon of strength and strategic vision. This report marks a pivotal moment in our journey, reflecting on the achievements, challenges, and transformative impacts of our mission to elevate the biopharmaceutical sector in India.

In this report, we present a comprehensive overview of our progress, highlighting key milestones, breakthroughs, and contributions to the broader healthcare ecosystem. We delve into the intricate details of our initiatives, offering insights into how our strategies have translated into real-world impacts. This report also highlights the diverse range of services now available as a result of ecosystem enhancement achieved through strategic investments in the mission. From bolstering infrastructure to forging strategic partnerships like Translational Research Consortiums, the Mission's achievements underscore the dedication of a collaborative network of scientists, subject experts, policymakers, and industry leaders.

As we reflect on the past years, we also look forward to the future with renewed vigour. The lessons learned and successes achieved thus far provide a solid foundation upon which to build. Our commitment to innovation, accessibility, and excellence remains unwavering as we navigate the evolving challenges of the biopharma landscape.

We extend our deepest gratitude to the all individuals and organizations whose contributions have been instrumental in realizing the vision of the National Biopharma Mission. Together, we are not only advancing science and technology but also making meaningful strides toward a healthier, more equitable world. We deeply appreciate your contributions and look forward to continuing this journey of progress and success together.

Thank you for your continued support and dedication.

Dr Raj K Shirumalla
Mission Director, NBM

Program Overview

Conceptualization of National Biopharma Mission-Unique Model for Long-term Sustainable Growth of India's Biopharmaceutical Industry

Mission

The National Biopharma Mission (NBM) is a government-industry-academia collaboration dedicated to 'Accelerating Discovery Research to Early-stage Development for Biopharmaceuticals'.

Vision

To enable and nurture an ecosystem for preparing India's technological and product development capabilities in biopharmaceuticals to a level that will be globally competitive over the next decade and transform the health standards of India's population.

OBJECTIVES

1. Development of advanced stages product **relevant to the public health need**
2. **Establishing and strengthening shared infrastructure facilities** for product development and validation
3. **Developing human capital** by providing specific trainings to address the critical skills gap across product development value chain.
4. **Creating and enhancing technology transfer** and IP management capacities and capabilities

May 2017: Approval from Cabinet Committee on Economic Affairs

April 2018: Loan agreement between Department of Economic Affairs and World Bank

Implementation of the Mission

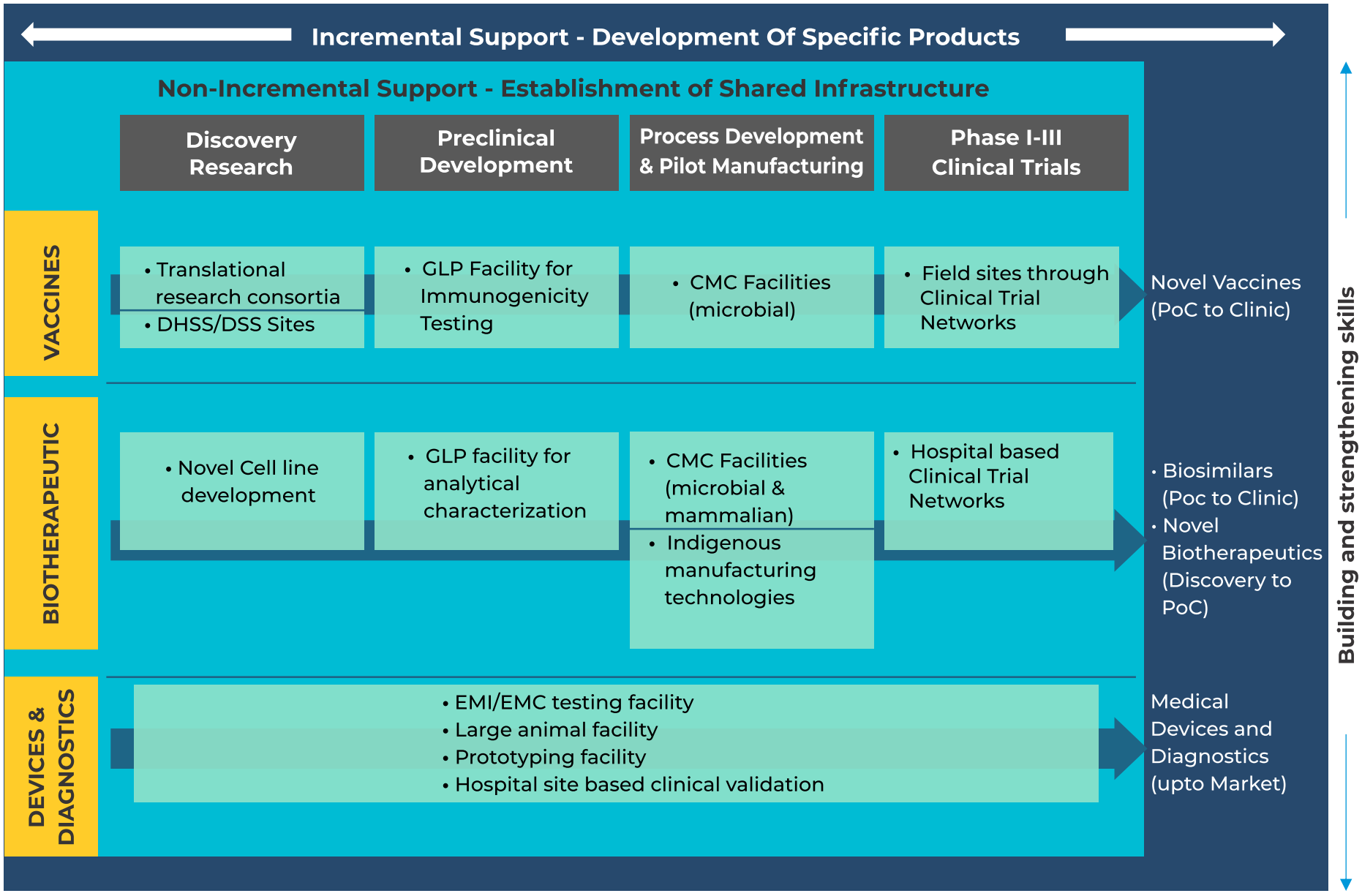
Department of Bio-Technology

National Bio-Pharma Mission Team

Gaps Identified in the Indian Biopharmaceutical Ecosystem (2017)

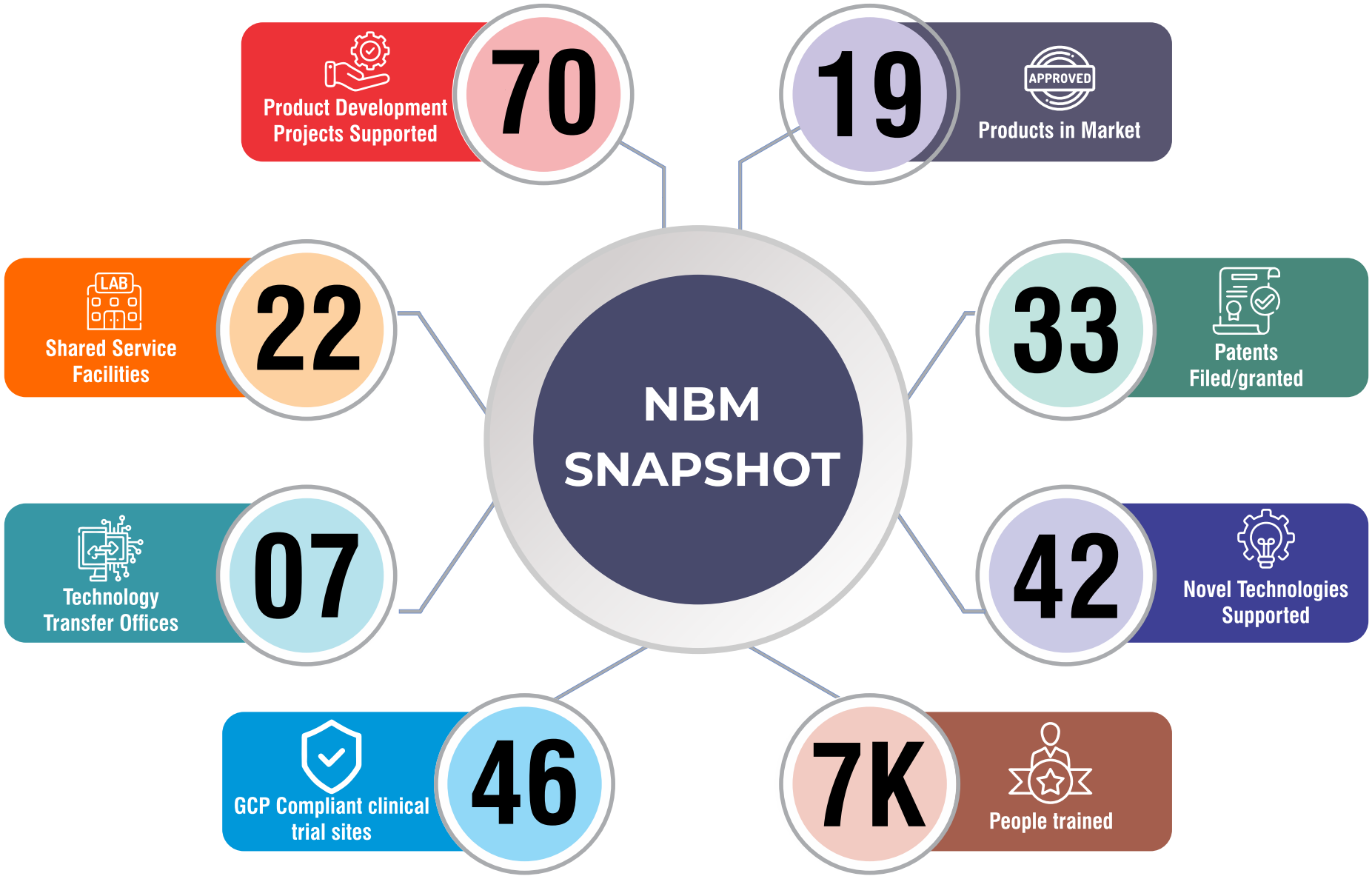
	VACCINES	BIOTHERAPEUTICS	MEDICAL DEVICES
Discovery & Early Development	• Few surveillance sites for understanding disease epidemiology • Limited product-oriented research in academia	• Limited novel biotherapeutics in pipeline • Import dependency for cGMP grade cell-lines and raw materials adding to cost of goods.	• Existing processes have limited scope to deliver products with defined functionality and benefits according to the market needs.
Preclinical Development	• Lack of validated immunogenicity assays for vaccine evaluation	• Service facilities for biophysical & functional characterization – limited, unaffordable	• Limited ISO certified prototyping testing, safety testing facilities
Process Development & Pilot Manufacturing	• Limited CROs for pilot scale manufacturing	• Limited CROs for GMP manufacturing and process innovations	• Limited availability and import dependency on electronic parts leading to delays in getting regulatory approvals
Phase I-III Clinical Trials	• Paucity of geo-tagged sites for community based Clinical trials.	• Limited access to well-defined population for Clinical trials • Trials based on published literature rather than real-world evidence of India	• Readily accessible Hospitals for pilot trials

National Biopharma Mission Program was Structured to Address the Gaps in Indian Biopharmaceutical Industry

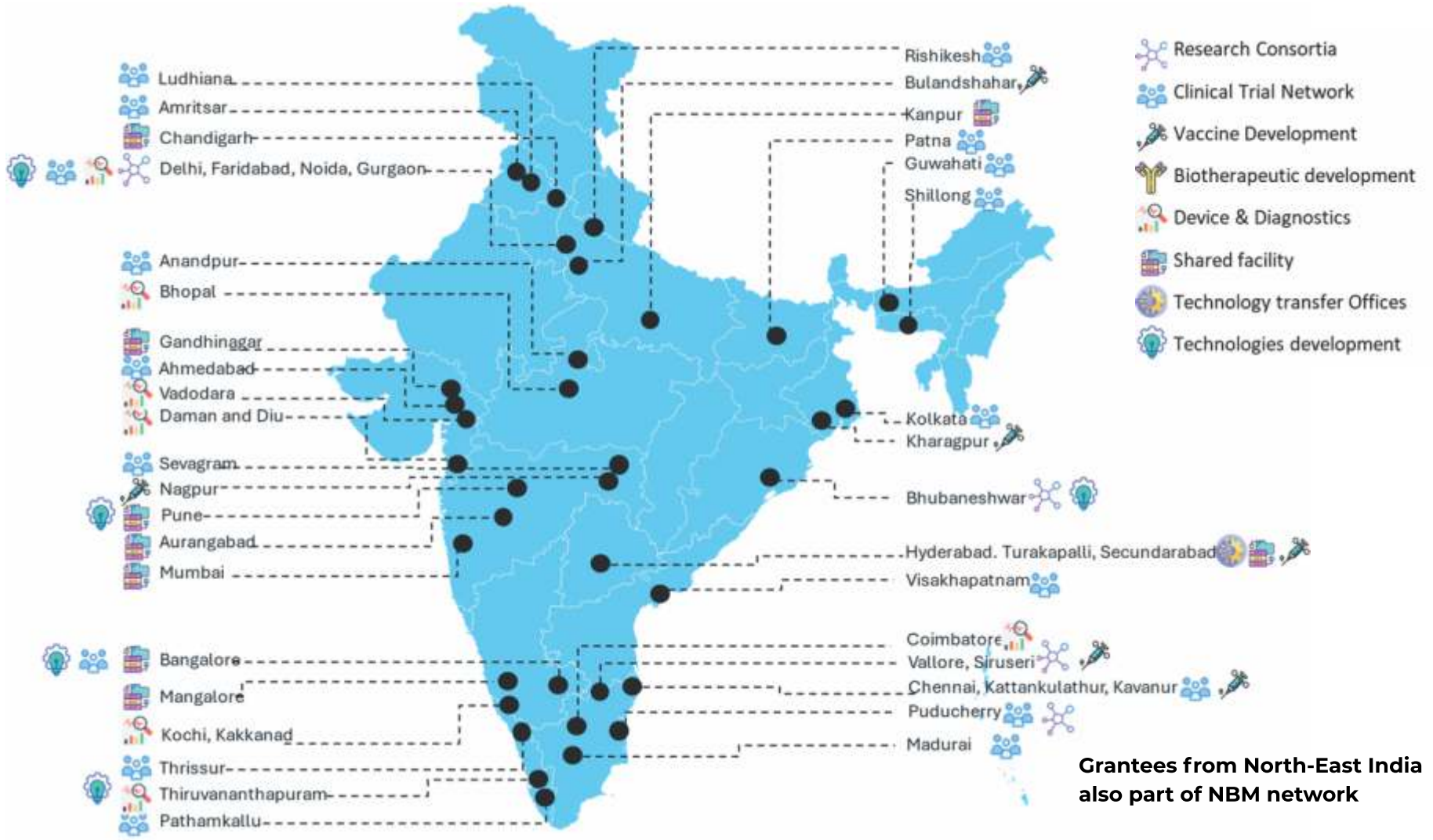


DHSS: Demographic & Health Surveillance System, DSS: Demographic Surveillance System, **GLP:** Good Laboratory Practice, **CMC:** Chemistry Manufacturing and Controls, **EMI/EMC:** Electromagnetic Interference and Electromagnetic Compatibility, **PoC:** Proof of Concept **GMP:** Good Manufacturing Practice

NBM SNAPSHOT



Representation of grantees across India

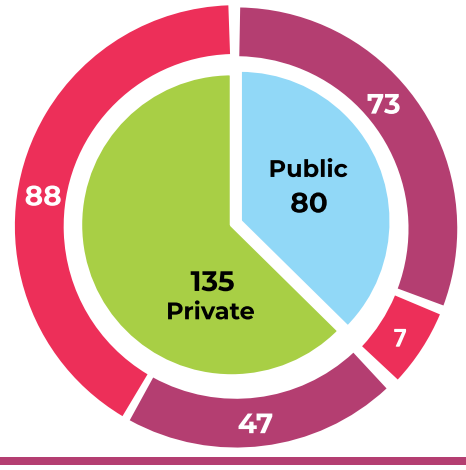


Grantees from North-East India also part of NBM network

Distribution of the grantees across Public & Private Sector and within Academia & Industry

215 Grantees across India

143 projects supported



** Industry Includes Start-ups, MSMEs, Society, LLP, Trust and large companies*

Methodology of Building the Impact Report

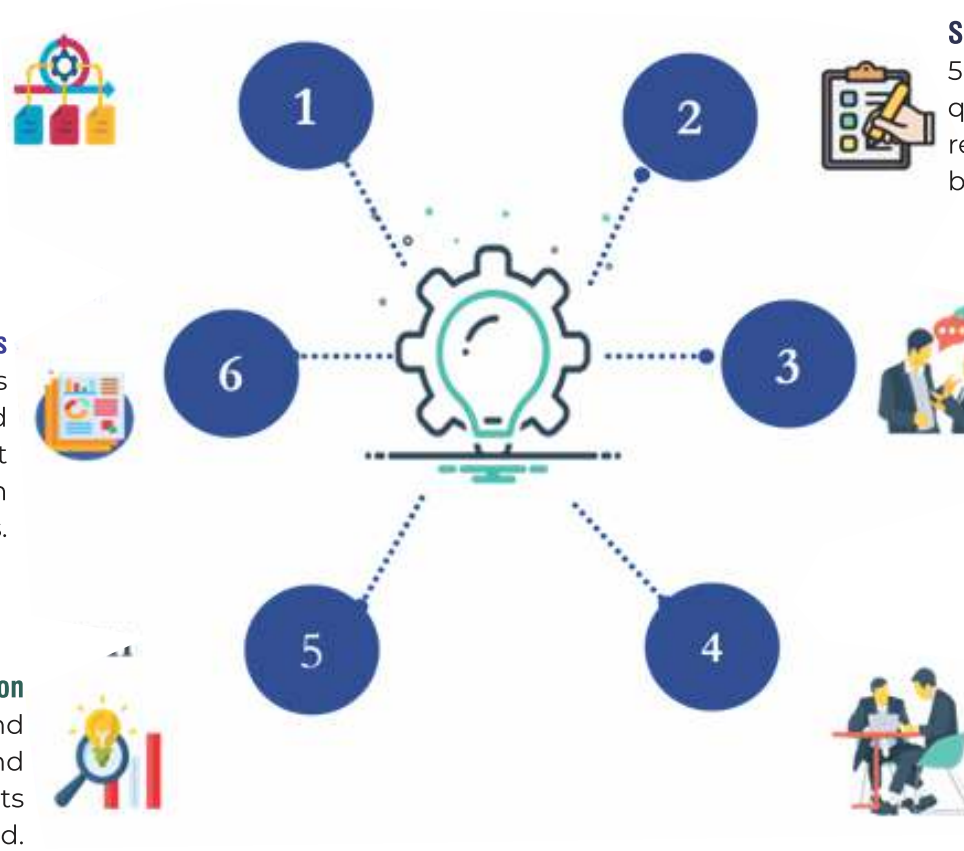
Methodology of Impact Analysis

DATA COLLECTION

Research & Analysis Framework
Build robust impact analysis framework to gauge complete Outcome of the mission.

Survey questionnaire
50+ customized survey questionnaire, circulated with regular follow-ups processed for better NBM-Grantee engagement

Landscaping reports
To understand needs and gaps within product development and ecosystem, market assessment was performed through comprehensive reports.



Communication Outreach
NBM helped connecting with grantees through emails and discussions, ensuring continuous support & effective coordination.

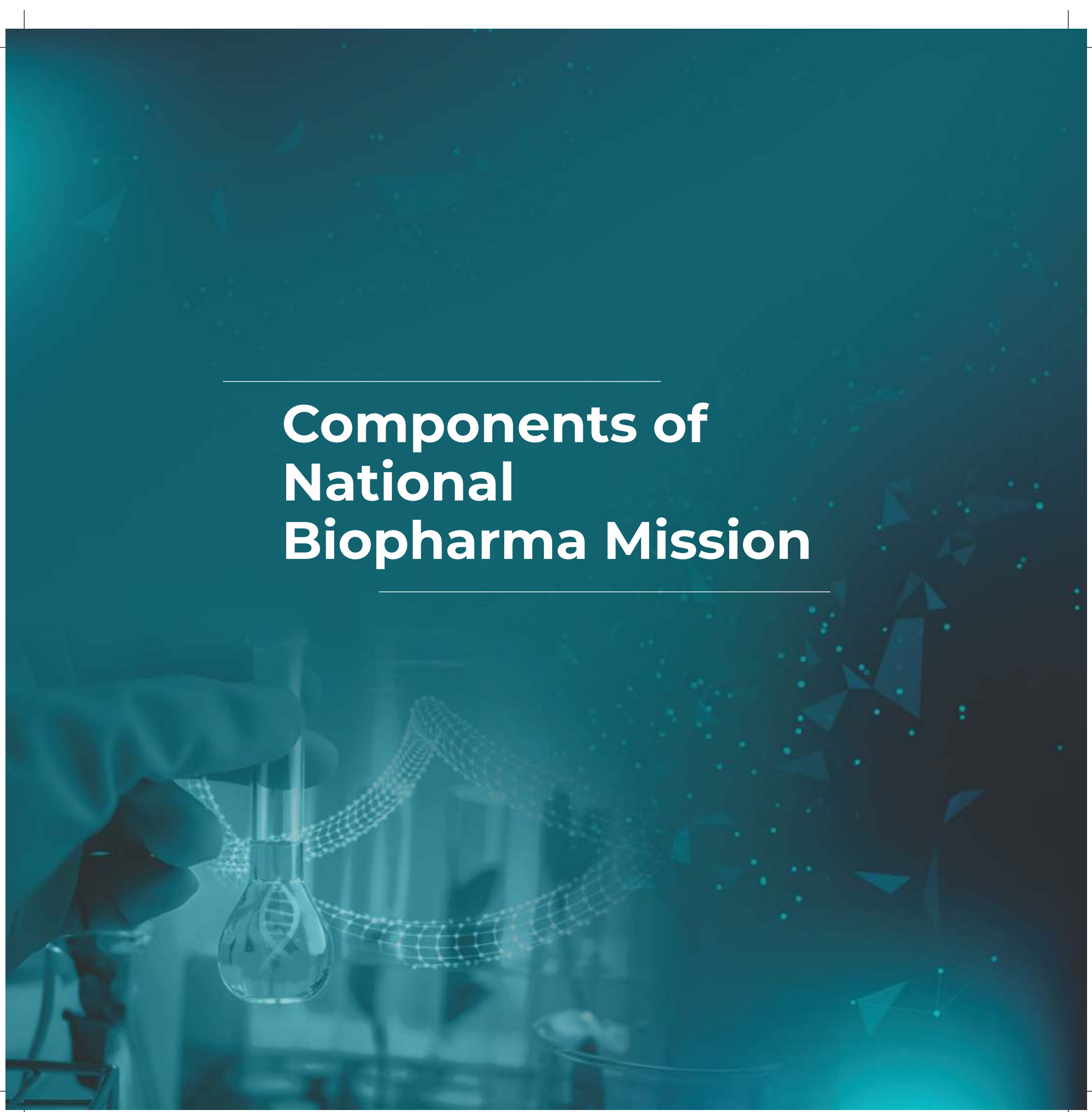
Insights Generation
Systematic data collection and analysis interviews and meetings, valuable insights were generated.

Interviews and Meetings
- 40+ grantees contacted across 7 verticals
- 30+ interviews and meetings conducted
- Held several 1:1 discussion to track progress

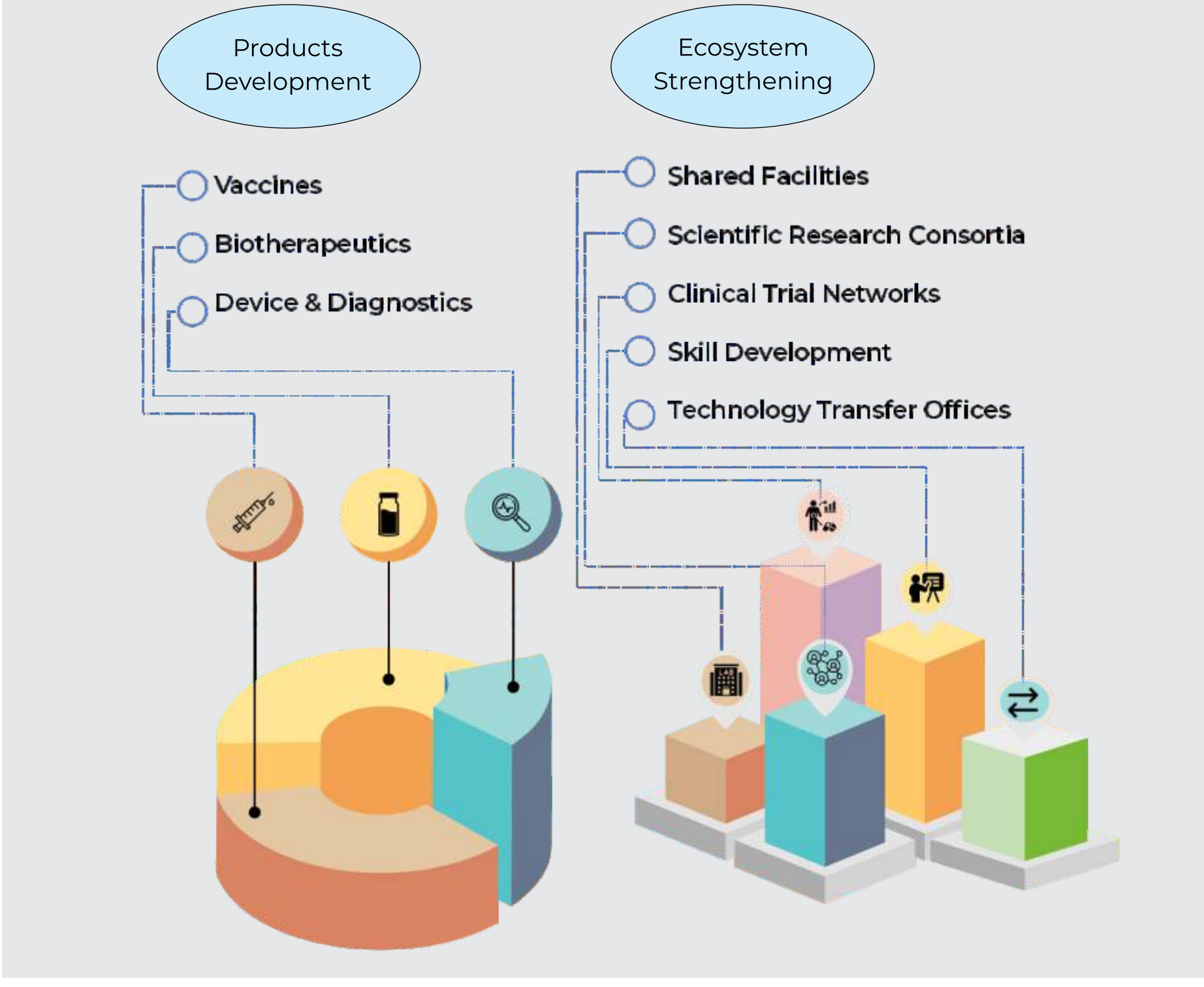
INSIGHTS GENERATED

- Status of Indian Biopharma Ecosystem from Mission initiation to current state
- Program Milestones v/s current outputs
- Resource Utilization
- Impact & Effectiveness of the Interventions
- Notable Accomplishments

Components of National Biopharma Mission



A two-pronged approach for Accelerated Product Development



Unleashing the Potential through Acceleration of Product Development

Component 1

Catalyzing Vaccine Development for Addressing Public Health Priorities

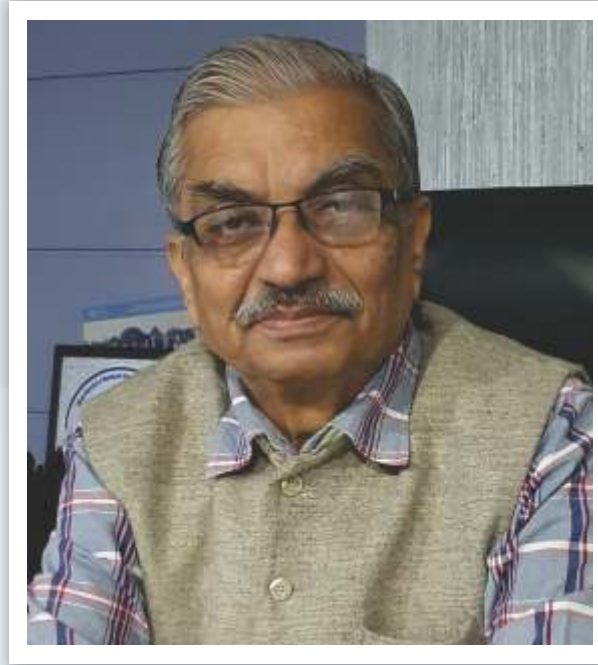
Message from Prof. N. K. Arora

I am privileged to serve as Co-Chair of the SAG and as a TAG member in NBM to provide scientific oversight and ensure successful implementation of the Program. It has been a rewarding experience to collaborate with a dedicated team of professionals to advance India's biopharmaceutical industry. NBM has facilitated the early development of promising novel vaccine candidates for high priority, complex infections by strengthening the ecosystem, increasing the success rates by providing support across the product value chain, and bringing them closer to the market.

Vaccines represent one of the most cost-effective strategies for managing infectious diseases. However, the discovery and development of novel vaccines face several challenges, such as limited understanding of the specific antigens required to trigger protective immunity due to genetic variability, predicting immunogenicity, efficacy, reactogenicity, or safety, lack of validated assays, access to well-characterized cohorts for clinical trials, and unclear regulatory pathways for novel vaccines, all of which contribute to delays in vaccine development.

NBM has outdone itself in achieving its target of bringing 2-3 vaccine products to commercialization, and has pioneered the development of vaccines for both diseases of public health importance as well as neglected tropical diseases. Their multipronged approach—supporting manufacturers with vaccine candidates through direct R&D funding and access to a network of industry and academic experts—has been instrumental in defining and streamlining the R&D pathway, resulting in more efficient and expedited product development. I extend my congratulations to NBM for its outstanding achievements in vaccine development since its inception.

I feel a profound sense of contentment in contributing to the establishment of a future where healthcare is universally available.



Dr. N.K. Arora
Co-Chair Scientific
Advisory Group for Vaccines

Accelerating Product Development - Gaps and Objectives

GAPS	OBJECTIVES
• **Reliance on high-cost Imported Vaccines:** For infections like pneumonia existing global vaccines are unaffordable for a large section of Indian population or may be at time unsuitable due to differences in the circulating strains • **Lack of Vaccines for India-centric Infectious Diseases:** Vaccines for high-burden diseases like dengue, chikungunya, cholera, and malaria are still unavailable. • **Limited Support for New Vaccine Development:** Several vaccine candidates are stalled in their initial stages of development due to a lack of trained human resources, infrastructure, and funding support for late-stage development and commercialisation.	**Supporting Vaccine Development for the diseases of National Priority** **Development of novel/new/next-generation vaccines**

Accomplishments

Target:
2-3 Products closer to Market

- Support provided for **12 Vaccine candidates**
- **4 Vaccines reached late-stage development**
- **2 Vaccines** received Market Authorisation

NBM support stage

Current Stage

Disease	Candidate	Grantee	PoC	Preclinical	Phase I/II	Phase 3	MA/EUA
	Universal Flu	Mynvax					
	Pneutger-15	Tergene					
	Dengue (LA)	IIL					
	Dengue Vax (VLP)	Sun Pharma					
	Cholera	BIBCOL					
	Chikungunya	BBIL					
	DNA candidate COVID	Zydus					
	Virosome COVID	Seagull					
	Protein Sub. COVID	Biological E					
	Re- BCG COVID	Serum					
	Protein Sub. COVID	Epygen					

MA-Market Authorisation, **EUA**-Emergerncy Use Authorisation

Vaccine Outcome

7 Diseases Targeted

Enteric Diseases
- Cholera
- HEV

Respiratory Diseases
- COVID
- Influenza

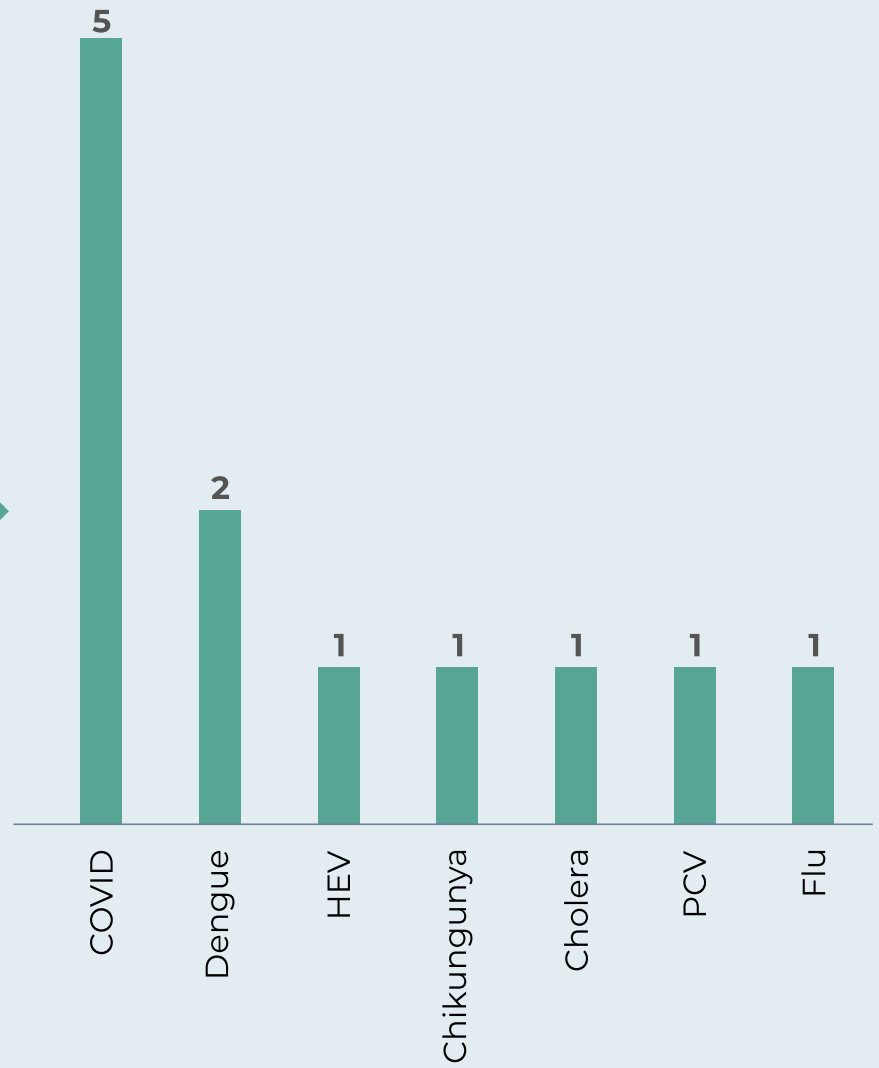
Vector Borne Neglected Tropical Diseases
- Dengue
- Chikungunya

Pneumococcal Disease

NBM fostered development of

12

Vaccine candidates



Impact

Vaccines supported till advanced stage of development - for diseases of concern in India	• India experiences an estimated 20-40 million dengue infections annually. Development of two vaccines for Dengue supported - Dengue-LA (Live-attenuated) which has completed Phase I clinical trial and Dengue-VLP (Virus-like particle) completed preclinical studies. • Supported development of first indigenous vaccine for Chikungunya which has completed Phase -2 clinical trial. • Development of two novel COVID-19 vaccine supported.
Novel manufacturing platform	• World's first DNA based SARS-CoV-2 vaccine, ZyCoV-D by Zydus Lifesciences Limited. • Vaccine has received Market Authorization Approval.
Next-generation vaccines that target geographically relevant circulating serotypes	• Supported development of Pneugter-15, a 15-valent Pneumococcal vaccine developed by TERGENE Biotech Pvt. Ltd and Aurobindo • Vaccine offers broader serotype coverage pertinent to Asia. • Anticipated to provide a 40% cost reduction compared to other currently available pneumococcal vaccines.
Vaccines suitable for introduction in Indian public health systems – India relevant	• Supported 'Universal Flu' influenza vaccine by Mynvax Private Limited, targeting the flu strains prevalent in India. • Formulated to be thermostable, eliminating the need for cold storage and mitigating related distribution challenges.

Details of key products

Vaccines

Pneutger-15 Pneumococcal Conjugate Vaccine (PCV) - India's first 15-valent Pneumococcal Vaccine

TERGENE Biotech Pvt. Ltd.

NEED

- High cost of the PCV vaccine in the Indian market.
- Procurement challenges due to the high market price
- Limited emphasis on PCV vaccines tailored specifically to meet Asian needs.

INTERVENTION

- NBM Funded Ph I to Ph III clinical trial and related expenses
- Immunogenicity evaluation assays (MOPA and ELISA) for the PCV vaccine were conducted at CRL, KIMS Bangalore, utilizing NBM-supported infrastructure
- KIMS Staff received training at a WHO reference laboratory in the U.S., leveraged by TERGENE Biotech Pvt. Ltd.
- Trainings of TERGENE staff for EHS compliances.

Current Status

- Make India self-reliant on an affordable and effective PCV providing protection against 15 pneumococcal serotypes compared to currently available 10, 13 and 14 valent vaccines
- Will be priced at ~40% lower than that of other Pneumococcal vaccines.
- Have potential to prevent millions of severe illnesses and save lives among children under 5 years age in India, revolutionizing the country's pneumococcal landscape

Freeze-dried Live-attenuated Tetravalent Dengue vaccine

Indian Immunological Pvt. Ltd.

NEED

The Dengue virus causes approximately 100 million cases annually, with cases in India surging from 28,292 in 2010 to 151,561 in 2017, highlighting the pressing need of an affordable dengue vaccine in India.

INTERVENTION

Funding and program management support for the development of 'Live-attenuated Tetravalent Dengue Vaccine'

Current Status

The Phase I trial report is being compiled and is expected to be submitted to the Indian regulatory agency by Q3 2024, after which, upon receiving necessary approvals from DCGI, Indian Immunological intends to proceed to Phase II clinical trial.

Universal Flu (Influenza Vaccine)

Mynvax Pvt. Ltd.

NEED	INTERVENTION
Efficacious, Affordable, adjuvanted, recombinant protein subunit vaccine for protection against human influenza virus	Funding and program management support for the development of Influenza vaccine

Current Status

Currently in preclinical development. CDSCO approvals for manufacturing at CMO site has been obtained.

BBV87, Chikungunya Vaccine

Bharat Biotech International Limited

NEED	INTERVENTION
Chikungunya is endemic in India, causing high morbidity annually, especially in adults. Development and licensure of a safe prophylactic chikungunya vaccine remains a crucial unmet need both in India and internationally.	Funding and program management support for Phase II clinical trial of BBV87 in India.

Current Status

Phase II clinical trial of BBV87 have been completed in India, with clinical data to be submitted to DCGI by August 2024, and the vaccine has been found to be safe and immunogenic in individuals aged 12-65 years in India, Latin America, and Thailand, as confirmed by BBIL's collaborator, the International Vaccine Institute (IVI).

Revolutionizing Biotherapeutics Development

Enhanced Access, Lower Cost, and Support Cutting-Edge Innovations

Message From Scientific Advisory Group for Biotherapeutics, Co-Chair

Prof. Govind Rao
Director, Centre for
Advanced Sensor Technology,
University of Maryland,
Baltimore County, USA

I have had the distinct honour of serving as Co-Chair of the SAG and a TAG member within the NBM. It has been a privilege to collaborate with a dedicated group of colleagues, working towards ensuring that the best ideas and capabilities materialise to drive the next phase of India's emerging biopharmaceutical industry. What is particularly gratifying is the concerted effort to ensure broad capacity development. We are establishing the groundwork to support a robust end-to-end capability for drug and device development, aiming to benefit both the citizens of India and the global community by enabling the cost-effective development of crucial vaccines, biologics, and devices.

Over the past five years, we have collectively engaged with various stakeholders, gaining valuable insights from each other. The interactions have been both collegial and professional, fostering many meaningful friendships. At India's inception, Prime Minister Nehru spoke of our work not being done until every tear shed from every eye was wiped away. Many decades later, Prime Minister Modi is investing to ensure that the next 25 years will witness the establishment of a global capability in India's industrial sector. Projections suggest that in 50 years, India will likely become the world's second-largest economy. To ensure that all its citizens have access to affordable healthcare, the pharma/biotech industry must overcome numerous challenges.

It was truly humbling to have the opportunity to contribute to laying the foundation for a healthy and prosperous future in which no tears are shed due to a lack of healthcare.

Accelerating Product Development – Gaps and Objectives

GAPS

- **Access to Biotherapeutics:** Products for diseases like cancer, rheumatology, and diabetes are available in India but in short supply and largely unaffordable.
- **Cost of Biosimilars:** Only ~30% cheaper than original products, but market competition could lower costs
- **Availability of Biosimilars:** Over 130 biotherapeutics will go off-patent globally in the next 5-10 years. India manufactures only 30% of them.
- **Focus on Novel Biotherapeutics:** Limited focus on developing novel biotherapeutics, cell lines, and clones for manufacturing biologics, all of which are imported

OBJECTIVES

Biosimilar Development

(Biosimilars with patent expiry 2015-2020)

Biosimilar Clone Development

(Clones for biosimilars with patent expiry 2020-25)

Novel Biotherapeutics Development

(novel mAbs, and cutting edge platforms such as CAR-T)

Biotherapeutics Accomplishment

Target:
2-3 Products
closer to Market

- Biosimilar Liraglutide for type-2 diabetes and pegylated interferon for Covid -19 reached market
- Biosimilar for Age related Macurlar Degeneration (AMD) advanced to Phase 3 Clinical trial
- 2 Biosimilars supported from PoC to Phase I clinical trial
- 3 biosimilars Supported from PoC to Preclinical stage
- Antibody drug conjugate (ADC), Chimeric-Antigen Receptor- T cell therapy (CAR-T), novel antibodies, mAb clones supported

NBM support stage
Current Stage

Disease	Category	Candidate	Grantee	PoC	Preclinical	GMP	Phase I/II	Phase III	MA
	Biosimilar	Insulin Lispro	NCL						
	Biosimilar	Liraglutide	Levim						
	Clone	Ranibizumab	NCL						
	Clone	Ranibizumab (Plt)	IIT D						
	Biosimilar	Aflibercept	Lupin						
	Biosimilar	Ustekinumab	Serum						
	Biosimilar	rHSA	Lazuline						
	Biosimilar	Trastuzunab	Serum						
	Biosimilar	Insulin Glargine	Stelis						
	Clone	Ramicirumab	Enzene						
	Clone	Golimumab	GeNext						
	Novel	Plasma therapy	Virchow						
	Novel	Human mAb	Bioklone						
	Novel	Antibodies	UDSC						
	Novel	Pegylated interferon	Zydus						
	Novel	Anti-VEGF	Theragen						
	Novel	ADC for NSCLC	Levim						
	Bio-better	2 anti-rabies mAbs	IIL						
	Novel	CAR-T therapy	TMC						

MA-Market Authorisation

Impact

Increased access to life saving biotherapeutics	• Supported development of Lirafit- Biosimilar of Liraglutide, indicated for type-2 Diabetes and Obesity which is India's first biosimilar. Launched at a price 65% lower than the innovator product. • Three new biosimilars previously unavailable in India are now in the pipeline for the treatment of Age-related macular degeneration, Immunological disorders, and Cancer.
Technologies to decrease biosimilar cost by improving manufacturing process for higher yield	• Continuous manufacturing process platform at IIT Delhi. • Economical manufacturing of Insulin Lispro through process innovation by National Chemical Laboratory (NCL) Pune.
Supported cutting-edge - novel biotherapeutics	• Indigenous cutting-edge CAR-T therapy for relapsed/refractory B-Cell acute Lymphoblastic Leukemia (B-ALL) in paediatric population (IIT-Bombay and Tata Memorial Hospital) in phase I/II clinical trial • Supported development of Novel anti-rabies monoclonal antibody, an anti VGEF antibody, and Antibody drug conjugate. All successfully completed preclinical studies.

Accomplishments

Biotherapeutics

Liraglutide Biosimilar

India's affordable Type-2 diabetes solution – the first Liraglutide biosimilar

- Levim Biotech LLP's Liraglutide biosimilar launched in India under **brand name 'Lirafit',** by Levim's marketing partner Glenmark Pharmaceuticals.
- Lirafit is a **GLP receptor agonist that increases glucose-dependent** insulin secretion and decreases inappropriate glucagon secretion.

Cost-effective, daily dose biosimilar now made available in India

Cost is INR 1855.00- 35% of the innovator's MRP of INR 5324.00 in India (65% discount)

Potential sales projections - INR 11,00,00,000 in India and INR 2,00,00,000 overseas.

At-home administration once per day. Require two auto-injection pens per month.

IMPACT

UNMET NEED

- Type 2 Diabetes affects over 100 million people in India; another 160 million are prediabetic.
- High-cost limits use of GLP-1 innovator drug in India; no biosimilar exists.
- The innovator drug has low penetration (0.001%) and a high cost (INR 5300).

INTERVENTION

Direct Funding for-

- Facilitated scale-up processes up to 200 L, Phase I and Phase – III clinical trial
- Supported indigenous development of pen device thereby reducing overall cost

Technical troubleshooting/hand holding-

- NBM ensured GCP compliance, clinical study reporting, and regulatory expert advice to the start-up

Product Launched GBI-2023

Launched with Glenmark Pharmaceuticals ltd. as marketing partner

TESTIMONIALS

While Levim had the skill set & the intent, the support from BIRAC was instrumental. For the last five years, the National Biopharma Mission has supported us with funds and scientific mentorship. Consequently, Levim has emerged as the first & only Indian company to have both the Phase 1 & Phase 3 clinical trials completed for Liraglutide. Further, our patented innovation led to the facile process for Liraglutide biosimilar, resulting in substantial cost reduction in treating Type-2 diabetes in India. Moreover, our technology shall enable us to develop similar next generation molecules. India requires more of this kind of molecule to make India the "DIABETES CARE CAPITAL" of the world.

Kadalmani Krishnan Ph.D.
General Manager, Levim Lifetech Pvt. Ltd.

"If Liraglutide Biosimilar matches our expectation, it would be an excellent addition"
– Dr. Ambrish Mittal

"The Indian Victoza is here!"
– Dr. Manas P Baruah

"Lirafit deserves an International Advisory board meeting"
– Dr. Abdul Hamid Zargar

"Lirafit is fit for the vast majority of Indian diabetics"
- Dr. Rakesh Sahay

"Another blockbuster Make in India product is here"
– Dr. Sunil Gupta

Clinicians prescribing Liraglutide


THE TIMES OF INDIA

A shift in diabetes and obesity landscape: Exploring India's affordable Biosimilar breakthrough

"A noteworthy advancement in this context is the current availability of a liraglutide biosimilar in India at 70% lower cost. This development not only expands the options available for type 2 diabetes (T2D) and obesity treatment but also addresses cost-related concerns, potentially making this effective medication more accessible to a broader population. By offering a more cost-effective alternative i.e. 1/3rd of the current cost of therapy, the biosimilar enhances the affordability and accessibility of liraglutide, potentially benefiting a larger population of individuals grappling with these conditions.

Compiled by the TOI medical team after inputs from
Dr. Hemant P. Thacker
MD (Bom), MRSH(Lond), FACE(USA), FACP (USA), FRCP(Edinburgh), Consultant Physician & Cardiometabolic Specialist, Director & HOD Medicine at Bhatia Hospital, Additional Director of Medicine at Jaslok Hospital, Senior Consultant Breach Candy Hospital Trust and Sir H. N. Reliance Foundation Hospital and Research Centre

Aflibercept Biosimilar

Developed by Lupin Ltd. Pune

Affordable quality treatment for patients with neovascular AMD (Age-related Macular Degeneration)

- Aflibercept has significantly higher binding affinity compared to other treatments. Bevacizumab, which is used off-label, and is not approved for ophthalmic purposes.
- Aflibercept binds to VEGF A, VEGF B, and PLGF, unlike its competitors which only bind to VEGF A.
- Among its competitors, Aflibercept has outperformed Ranibizumab with market values of 8 billion USD vs. 3 billion USD, respectively.

Huge global market approx 10 billion USD (IMS Q4 2022)

Lupin to launch Aflibercept at 40% below EYLEA's anticipated MRP of INR 45,000 per unit in India

Aflibercept requires fewer injections compared to existing alternatives

Price reduction aims to boost Aflibercept affordability and accessibility as compared to drugs like Bevacizumab and Ranibizumab

Impact

UNMET NEED

- Age related macular degeneration (AMD) accounts for 8.7% of all blindness worldwide.
- The estimated population of those suffering from AMD worldwide was 196 Mn in 2020.
- Projected prevalence to increase to 288 Mn by 2040 due to increasing lifespan globally and Westernization of diet and lifestyle.
- Lack of support towards introducing biosimilar Aflibercept in India (Though Aflibercept was approved much earlier).

INTERVENTION

Direct Funding

- From PoC to phase III clinical development

Program management support

- NBM ensured technical expert advice
- Program management support

Enabled training of ~50 cross functional manpower across domain areas of research, manufacturing and QC

"Lupin's Aflibercept would bring an affordable quality treatment for patients with neovascular AMD and hence is extremely relevant to the Indian society".

"This would also support the make in India campaign for such complex molecules utilizing existing skills, knowledge and facilities in India".

Chimeric antigen receptor-T (CAR-T) Cell therapy

TMC Mumbai & IIT Bombay

- Indigenously developed CD-19 receptor targeting CAR-T cells for paediatric patients with relapsed/refractory B-cell acute lymphoblastic leukaemia (B-ALL)
- Successful implementation will significantly enhance the quality of life for patients – with fewer hospitalizations and reduced disease-related symptoms
- Featuring cost-effective Indigenous manufacturing of cell-based immunotherapy products at the CAR-T Cell Therapy Centre at ACTREC, TMC

Will be commercially available in India for approximately ₹35 lakh

Transformative for India's approach to cancer treatment

Affordable alternative to existing CAR-T cell therapies

Demonstrated minimal side effects, including no neurotoxicity

Impact

UNMET NEED

- CAR-T cell therapy, a groundbreaking treatment for haematological malignancies, traditionally costs between ₹3-4 crore per patient globally.
- Making it inaccessible to many patients.
- An affordable and effective therapy that meets India's healthcare needs.

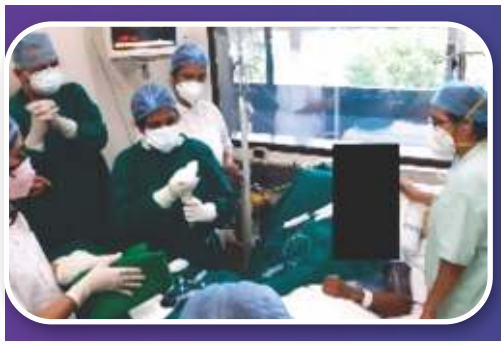
• INTERVENTION

Direct Funding

- Bench-to-bedside development of the first-in-India CAR-T cell therapy was supported for Ph II to Ph III clinical development

Program management support

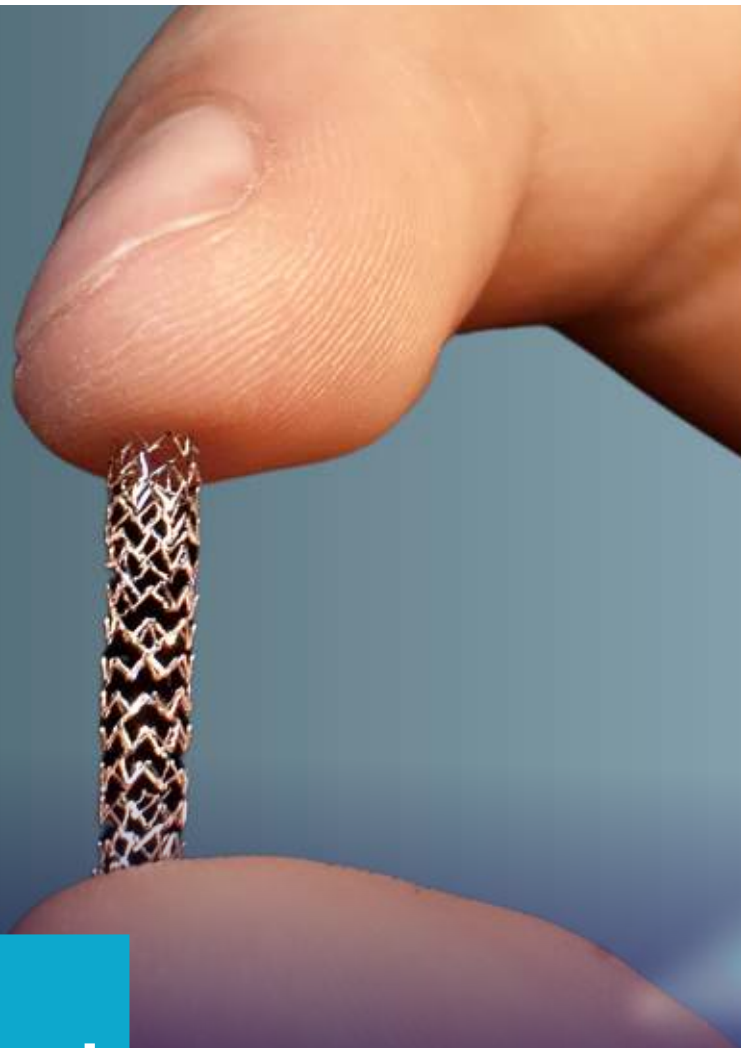
- NBM ensured technical expert advice, Program management support, and training for indigenous development of technology.



CTCTC (CAR-T cell therapy at the CAR-T & Cell Therapy Centre) has presented several abstracts at multiple international and national forums for advancing cell and gene therapy research, enhancing visibility of India's contributions to CAR-T cell therapy, and fostering more international collaborations.

Empowering Indigenous Medical Devices & Diagnostics Development

for Enhancing Accessibility, Affordability, and Reduced Import Dependency



Insights From Scientific Advisory Group for Devices and Diagnostics, Co-Chair

Dr. N. R. Jagannathan

FNA, FASc, FNASc, FAMS, FISC, FISMRM (USA)

Distinguished Visiting Professor, Koita Centre for Digital Health (KCDH), IIT Bombay, Mumbai

It was a privilege for me to serve as a Co-Chair of the Scientific Advisory Group (SAG) on Devices & Diagnostics and as a member of the Technical Advisory Group (TAG) of the NBM program of BIRAC. I was fortunate to have a team of highly dedicated colleagues with expertise in various branches of devices and diagnostics, which made my job much easier. We all had one goal. That is to ensure that the novel and workable ideas (along with the capabilities of investigators/ group) need to be funded and nurtured. In fact, such sanctioned projects were periodically monitored by a 3-member project monitoring committee (PMC) for successful implementation. We aim to take these projects to the next level so that our country can produce indigenous devices and diagnostic equipment with the participation of industries, especially in the healthcare sector, and thus become self-sufficient. Additionally, these programs are expected to provide developmental capabilities for mass production that would benefit India in the long run and drastically reduce the capital costs of these devices.

This, in turn, would help India to provide health care to villages at an affordable cost to the people of our country. During the course, we were also able to build good human resources in various domains of devices and diagnostics. NBM had many successful stories and to mention one of them is the launch of the indigenous MRI scanner manufactured within India. This 1.5 tesla MRI scanner was launched by the Hon'ble Minister of Science & Technology Dr. Jitender Singh on August 31, 2023. This would reduce the capital cost of the MRI scanner and the cost of the MRI examination, considerably, thus facilitating MRI for a large number of people of India, who otherwise cannot afford it. Overall, as a Co-chair it was satisfying and a learning experience for me to work with dedicated expert colleagues and able NBM and BIRAC staff. I am sure with such programs we are on a path of a healthy and prosperous India.

Accelerating Product Development – Gaps and Objectives

Gaps

- **High-import dependency:** 80% of medical devices in India are imported.
- **Suitability issues:** Imported devices often designed for industrialized countries may not suit the Indian ecosystem due to design challenges, infrastructure needs, and usability gaps.
- **Affordability:** High costs of imported devices raise healthcare expenses and out-of-pocket costs.

Objectives

Development of medical devices and diagnostic products

(Wound Management, Trauma and Emergency medicine, Surgical Tools, implants)

Development of core technologies and products

(Ischemic Heart Diseases and Chronic Obstructive Pulmonary Disease, Endoscopy and MRI scanner)

Medical Devices and Diagnostics Achievements

Target: 3-4 Products closer to Market

- Supported 29* Devices & Diagnostics development projects, of which 11 products received market authorization

Devices

Disease	Candidate	Grantee	Design	Evaluation	Preclinical	Clinical	Regulatory Approval	Market Authorization
	"Refirm" Dental Implant System	Intessence						●
	Endoscope	Univlabs						●
	Indigenous MRI scanner	Voxelgrids						●
	Material for bioabsorbable implant (PLA)	OrthoCrafts				●		
	Fusion Imaging Endoscopy	Imlic			●			
	SAANS- multifunctional neonatal breathing support	InnAccel						●
	Smart Endoscope	HTIC				●		
	Titanium heart valve	TTK				●		
	Velgraft	DATT				●		
	Vision IBPwire and Vision VPS20 Console	VASMED		●				
	VLarynx -Video Laryngoscope device	VPHORE				●		
	FlexiOH Immobilization Cast	JC Ortho						●
	Real time High frequency ECGs	Carditek					●	
	Mandibular bone augmentation	Amrita Vishva Vidyapeetham				●		

Diagnostics

Disease	Candidate	Grantee	Assay Development	Standardization	Validation	Regulatory Approval	Market Authorization
	ANTIGEN Antibody detection	ubio					●
	Covid first RT PCR Test Kit	Mylab					●
	Covid detection test	SciGenom		●			
	Covid Detection Kit	Denovo			●		
	Molecular diagnostic kit	SHC Shine		●			
	Molecular diagnostic kits	Huwel					●
	Molecular transport medium for covid	Levram					●
	qPCR diagnostic Kit for COVID-19	YAATHUM					●
	Lateral flow immunoassay Device	GGSIU				●	
	ELISA Covid Detection Kit	Achira					●
	Electrochemical Covid Detection	PathShodh			●		

Impact: Medical Devices and Diagnostics

Encouraged indigenous Medical Device development to improve accessibility, affordability and reduce import dependency

- ‘India’s First affordable MRI scanner, by Voxelgrids Innovations Pvt. Ltd., is available in stationary and mobile configurations.
- The TTK Chitra Heart valve by TTK HEALTHCARE Ltd. meets global quality standards and offers an affordable alternative to imported valves
- A novel dental implant by Intessence Solutions Pvt. Ltd. is now available at a competitive price range of 3,500 to 4,000 rupees per implant.

Enhanced accessibility by developing medical devices with compatible design

- Advanced endoscopy system developed with features such as multi-spectral CPU/GPU imaging system instead of existing FPGA system – suitable for tier 2 and tier 3 hospitals at more affordable cost, thereby reducing out-of-pocket expense to 1/3rd.

15 Novel products supported

11 Products commercialized

25 Indigenous products developed

6 Types of diagnostic technologies supported

8 Types of medical device technologies supported

Accomplishments

Magnetic Resonance Imaging (MRI) Scanner

Developed by Voxelgrids Innovations Pvt. Ltd., Bengaluru

India's First MRI scanner with stationary and mobile configurations

Enhanced imaging capabilities 1.5 Tesla Helium free superconducting magnet with a gradient amplifier, both of which are built in India

Reducing import dependency - offering affordable cost for improved healthcare outcomes

Impact

Need

- Lack of affordable, cutting-edge technology in this space.
- Low MRI penetration: Access to MRI machines is 1/10 to 1/15 per million population in India compared to the US and Japan.
- Mobile MRI scanners: To provide broader access.

Intervention

- ISO13485-certified facility for superconducting magnets
- Equipment for field mapping, gradient amplifier, prototype machines, mobile trucks
- Cryostat welding and customizing mobile trucks development
- Mentoring and monitoring by Program Monitoring Committee and SAG

Progress

Received Market Authorization

Offers 40% lower cost compared to other MRI scanners

We were privileged to have Dr Jitendra Singh Hon'ble Minister of State (IC), Ministry of Science & Technology, and Ministry of Earth Sciences; Minister of State, PMO; Ministry of Personnel, Public Grievance & Pensions; Department of Atomic Energy; and Department of Space, Govt. of India, for launching MRI Scanner.

Titanium Heart Valve Model Tc2

Developed by TTK Healthcare Pvt. Ltd., Thiruvananthapuram

Improved thrombo-resistance and reduced bare metal exposure to the bloodstream by Titanium nitride (TiN) coating on frame surface.

Enhance the MRI compatibility by changing the frame material from Haynes 25 (cobalt alloy) to Ti6Al4

Completely indigenizing the technology, these valves are designed to enhance blood flow through increased flow area, effectively improving patient outcomes

Impact

Need

- Rheumatic heart disease (RHD) caused 319,000 deaths and 33.4 million cases globally; India had 13.17 million cases and 119,100 deaths in 2015.
- Tissue valves deteriorate in 5-7 years due to calcification creating high demand for artificial heart valves.
- Large-scale manufacturing of porcine or bovine valves is limited by poorly organized pork and beef industries.
- The Indian market requires about 30,000 heart valves annually and relies on imports.

Intervention

- NBM financially supported technology to complete pilot-scale clinical investigation.
- Regular mentoring and guidance from experts.

Progress

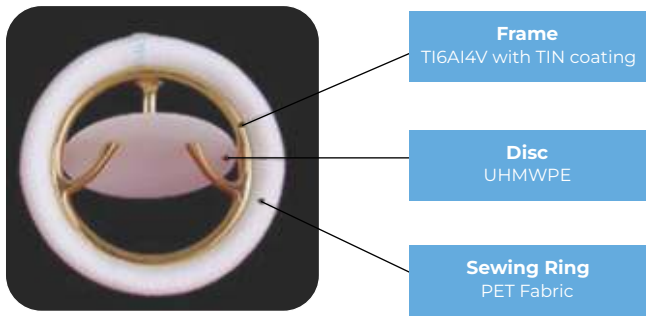
- Completed manufacturing of 100 samples for pilot scale clinical investigation
- Completed Implantation of valves in 40 patients and submitted pilot scale clinical investigation report
- CDSCO test manufacturing license received
- The technology now entering in multi-centric clinical trial.

The introduction of the TC2 artificial valves represents a significant advancement in cardiac health technology.

The project's extension due to NBM's support allowed research team to navigate the challenges posed by the COVID-19 pandemic and complete the clinical trials successfully. The NBM grant enabled project to progress smoothly, including the funding needed for pilot study and trials. Approval from NBM facilitated next steps of project and helped ensure the project's continuity.

Dr Anupam V Raj

Dy. Manager, Research at TTK HEALTHCARE LIMITED



Rigid Tilting Disc TTK Chitra–Titanium Heart Valve Model Tc2

SmartEye – Technology Platform for flexible endoscope

Developed by HTIC, IIT Madras in collaboration with Mitra Medical Services Pvt. Ltd, Delhi

Improved diagnosis with multi spectral imaging and intelligent image fusion techniques

Increased accessibility, and reduced turnaround time & cost.

Reduced import dependency

Impact

Need

- High market demand
- Lack of indigenous endoscopy product
- Dependency on imported accessory parts
- Limited innovations required as per the application needs

Intervention

- Financial support, regular monitoring, and expert guidance were provided to successfully complete the project.
- This enabled the company to bring the novel technology to local and international markets.

Progress

- Development of the device as proposed has been successfully completed
- Application to CDSCO is under process.

Indigenously developed for improved access and affordability

Grant support from NBM significantly accelerated the development of the affordable endoscopy device in the MedTech space, where funding sources are scarce. Technical support through SAG meetings provided expert opinion and feedback that were critically instrumental in product design. Suggested the creation of avenues for knowledge sharing and expertise exchange. Workshops, programs, or memberships focused on medical device development could accelerate product creation and innovation.

-Dr Mohanasankar Sivaprakasam

Professor of Electrical Engineering, IIT Madras

SE+v2 Advanced Multispectral Scope with SE3 Video Processor

Scope Tip with Blue LED ON

Scope Tip Components

Human Bone Marrow Derived Mesenchymal Stem Cell Based VELGRAFT Technology

Skin substitute on wounds of Diabetic Foot Ulcers, successfully developed by Datt Mediproducts Pvt. Ltd., New Delhi

VELGRAFT is immunologically inert ensuring well-tolerance and less rejection from the graft recipient.

Optimized cold transport system with real time monitoring and delivering in short duration

Increased accessibility, and reduced turnaround time & cost.

Impact

Need

- Treatment failures in diabetic foot ulcer patients
- Multiple complications are seen after conventional methods of the treatments.
- Critical requirement of alternative novel and effective treatment
- Lack of indigenous product in this space.

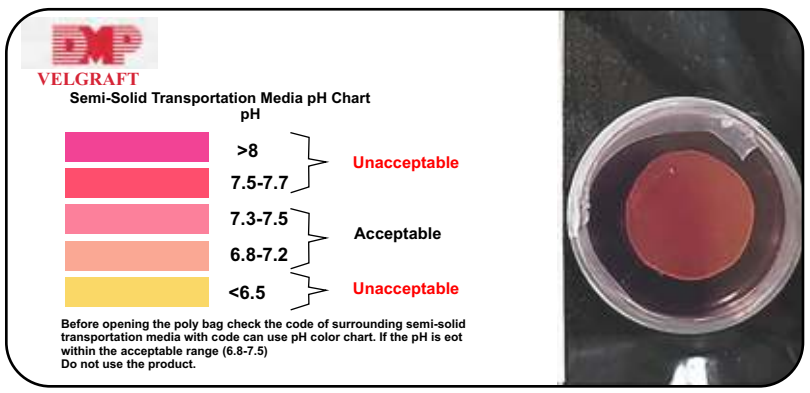
Intervention

- Financial support, regular monitoring, and expert guidance were provided to successfully complete the project.
- This enabled the company to bring the novel technology to local and international markets.

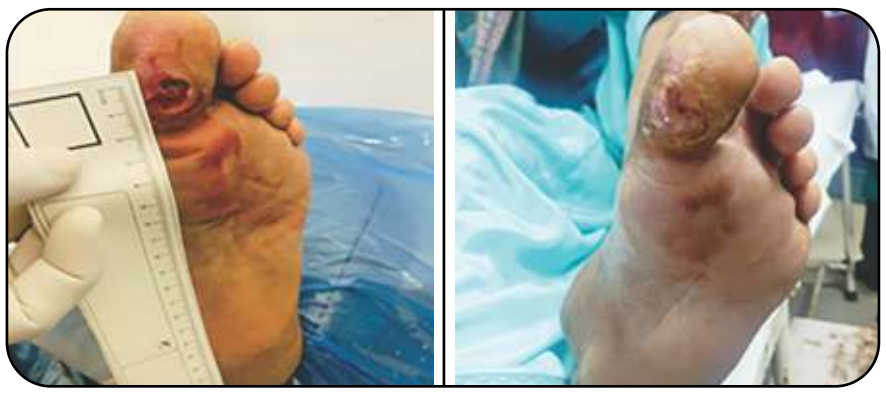
Progress

- No drop out during the patient's wound healing was observed.
- Positive feedback has been generated from the patients and clinicians.
- Phase I Clinical trials successfully conducted and application to CDSCO is under process.

Supported Indigenous development for high unmet need



AVELGRAFT Prepared and placed in in semi-solid Transportation media



Before Treatment **After Treatment**

High Frequency ECG device

Developed by Carditek Medical Device Pvt Ltd, Bengaluru

Fully Indigenized Real Time ECG tool

Reduction of unnecessary tests and diagnostic cost

Improved sensitivity than conventional ST analysis in ECG

Increased accessibility, and reduced turnaround time & cost

Universally accessible without ambient environment

Impact

Need

- Limitations of conventional ST analysis utilized in ECG.
- Tedious operation of the conventional system.
- Lack of cardiac emergency tools for onsite monitoring of the patient
- Lack of indigenous technologies in the sector of ECG.

Intervention

- NBM has supported development of high-resolution device High frequency ECG HFECG and µHFECG

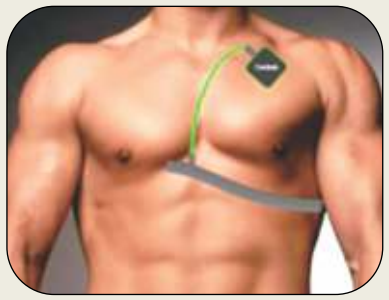
Progress

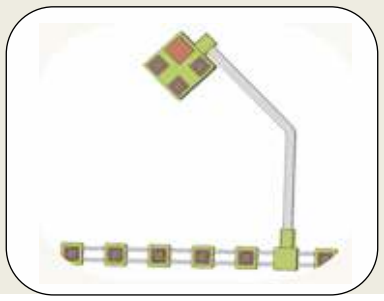
- Successful pilot scale clinical trials
- Clinical validation is ongoing

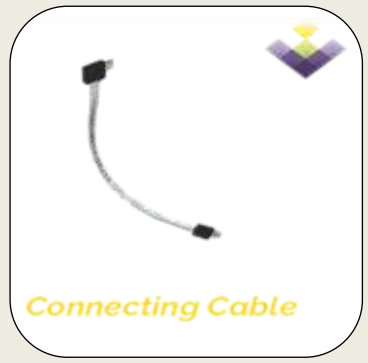
Enhanced ease of operation

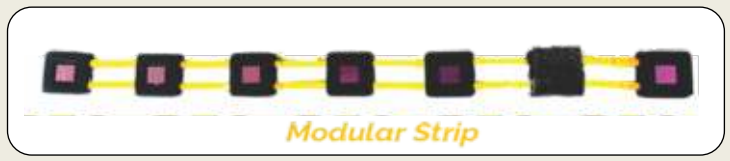
Simplified and Compacted

Development and pilot batch manufacturing of HF-ECG patches









Transcending product development

for affordability and accelerating bioprocessing

Decreasing Import Dependency in Manufacturing Technologies for Affordable Biopharma Product Development

Strength

- **Robust manufacturing technical expertise** to produce several biologics at an affordable price
- **Highest (62%) vaccine production** across the globe
- **Caters to > 140 countries with > 1.45 billiondoses** annually with Highest Regional Market growth

Hurdles

- 56% of raw materials **not being manufactured in India**
- 27% of **raw materials is being imported** despite existing manufacturing capacity, owing to hurdles related to **technology access, QA/QC, and infrastructural capacities**

Supported local development initiatives to reduce reliance on imports and lower manufacturing costs.

Prioritized technologies based on cost contribution and existing capacities:
Chemically Defined Media, Bioreactors, and Information Management System platform

Source: IATA Knowledge hub, Vaccines and the India market 2021
S. Plotkin et al. / Vaccine 35 (2017) 4064–4071; Interviews with industry experts cited in S. Plotkin et al. / Vaccine 35 (2017) 4064–4071

India's 1st Single Use Bioreactor system: CellBRx™

by OmniBRx Biotechnologies Pvt. Ltd., Ahmedabad

Development of first and only bioprocess technology indigenously developed in India and successfully commercialized worldwide

NEED

- No Indian manufacturer for small scale single use bioreactor for accelerated process development
- Only a few suppliers like Sartorius and Eppendorf render the cost very high (~ 5 Cr).

PROJECT SUPPORTED

NBM support development of CellBRx 50L & 200L SUBs platforms suitable for production scale which is world's largest and most scalable bioreactor platform to manufacture vaccines and viral vectors

Current Stage:

MARKETED

IMPACT

- Great potential to help biopharmaceuticals and stem cell therapy centres to meet market demand and to reduce the cost of drugs, significantly.
- This disruptive technology is considered as major import substitute for single use bioprocessing products & market for India.
- Provides process scalability and reduced batch-to-batch variability and minimizes process failures in large scale operations.
- Automated, integrated (close loop) & robust platform for vaccine manufacturing with the smallest facility footprint.
- Platform validated by serum institute & Biological E

70+ total staff employed

Several Units Sold in Generating revenue

OmniBRx Biotechnologies Pvt. Ltd. is the India's first bioprocess engineering company engaged in development & manufacturing of Single-use bioreactors for large-scale vaccine & Viral vector production.

-Ravindra Patel
MD & CEO
OmniBRx Biotechnologies Pvt. Ltd.

Cell Culture Media with Feed Supplement

by Himedia Laboratories Pvt. Ltd., Nashik

Decreasing Import Dependencies for Manufacturing Technologies

NEED

- No Indigenous media is available in India.
- Imported culture media has significant costs and often results in prolonged waiting periods due to dependencies on foreign suppliers.
- Imported culture media for CHO cells commercial production costs 2000-3000 INR/Litre.
- A single 1 kL batch needs 30 Lacs INR media.

PROJECT SUPPORTED

- NBM support enabled the establishment of a comprehensive media optimization system by incorporating various essential components and advanced analytical tools like Nova bioanalyzer, UHPLCs, and ICPMS.
- Developed Indigenous chemically defined Serum-free medium with feed supplements ensuring faster media availability.
- Incorporation of recombinant growth factors and amines in the culture media have been instrumental in boosting the overall efficiency of the new media formulation.

Current Stage:

MARKETED

IMPACT CREATED

- This product will result in cost reduction of culture media cost by up to 50% by offering CHO CDSFM media at less than 10 USD per litre, with a targeted price of 5 USD per litre for bulk orders.
- Cell culture media developed is specifically tailored to meet the requirements of Indian Biopharma CHO clones.
- Optimization process ensures a custom fit and enables swift delivery of media solutions.
- Reduced turnaround time to as short as short as 3-4 weeks for both small and bulk quantities of media, up to 5000 L.
- Cell culture media will ensure affordability, and will contribute to the Government of India's vision of making affordable biologics accessible to all.

LIMS (Laboratory Information Management System)

by LAB ICONICS Pvt. Ltd., Hyderabad

Development of a quality management system electronic platform for the Biopharmaceutical Industry

NEED

No availability of an economical, single purchase and multiple-user quality management software (s) system for the biopharma Industry

PROJECT SUPPORTED

- Development of indigenous software for Quality management and Electronic Lab Notebooks that meet the regulatory requirements of USFDA 21 CFR Part 11 and ICH guidelines, respectively, and comply with the GAMP 5 requirements.
- Three software including LIMS, ELN and a backup system were developed

CURRENT STAGE: MARKETED

Received Best Innovative Technology Award at 'Analytica Anacon India Lab Expo-2022', Mumbai

IMPACT CREATED

- Designed to improve lab productivity and efficiency, enhance the effectiveness of laboratory operations, and maintain a digital trail of samples, experiments, lab workflow, instruments, and inventories.
- Efficiently manages the batches/samples with configurable workflow, easy to track and access the sample history. Highly secured. Comprehensive Audit Trails by tracking the revisions of every transaction with the event.
- 700 Scientists have access to Lab Iconics LIMS & ELN application.

Generated employment for 46 people and will soon be expanding by another 20 people

Revenue being generated , several units sold

IMPACT SUMMARY

Product Development

Contribution of NBM in product development life cycle

Gap Mapping & Prioritizationa

- Vaccines prioritized based on WHO recommendations, GAVI priorities, IAP recommendation and Indian vaccine development pipeline.
- Biosimilars prioritized based on disease burden and patent expiry (2015-2020 & 2020-2025)
- MedTech product development was guided by disease need, product development gaps and need for indigenization.
- Facilities prioritized based on industry, academia consultations and product development needs.

Funding

- Products funded for multiple domains of product development e.g., Capex, manufacturing, manpower, consumables, and outsourcing
- Also funded capacity building, regulatory accreditations and manpower trainings to accelerate product development.

Scientific Mentorship

- A Scientific Advisory Group (SAG) formulated for product development, including national and global experts, and Key Opinion Leaders (KoLs)
- Facilitated monitoring and aligning scientific strategies with program objectives, provided recommendations on priorities, and the acceptance of new strategies at any stage.

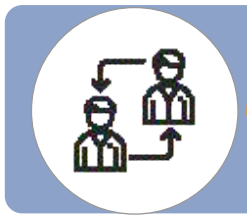
Building Collabs. & Partnerships

- Established linkages between product developers and ecosystem enablers for accelerated product development
- Linkages for technology transfer wherever necessary

Facilitating Trainings

Funding for trainings provided to meet specific need in product development cycle, e.g.

- Training on design controls in medical device development
- Hands on training of medical device to clinicians for faster & easy uptake
- Trainings of virus sample handling & processing for vaccine development against viral disease
- Environmental compliance and biomedical waste management rules trainings



Engaging Consultants

- Engagement of consulting partners for Knowledge Management, clinical trial regulatory/advisory and data safety management
- Engaging stakeholders including industry, academia and start-up for designing RFPs and projects
- Impact analysis of product development portfolio

Navigating the Uncharted Frontiers

Building a robust Ecosystem for Biopharma Innovation

Component 2

- Shared Infrastructure
- Translational Research Consortium
- Technology Transfer Offices
- Clinical Trial Networks
- Skill Development

Leveraging Comprehensive Strategies to Revolutionize the Biopharma Ecosystem at "all Stages" of Product Development

	Preclinical Development	Testing and Evaluation	Late-stage clinical trails
Vaccines	Translation Research Consortia	GCLP Compliant Validation Lab	Clinical Trial Network
Biotherapeutic	Development of novel cell lines/clones and expression vectors GLP compliant analytical facility	Cell line Repositories Process Development Lab and GMP Manufacturing	Hospital based Clinical Trial Network
Device & Diagnostics	Development of core technologies Prototyping Facility	EMI/EMC Testing Facility Large Animal Facility	Hospital Based Clinical Trial Network Manufacturing of Diagnostics kits

Skill Development at all stages

Establishment of Tech Transfer Offices

Building Shared Infrastructure

for testing & manufacturing Biopharma Products

Shared Infrastructure

Infrastructure Strengthening to Support Vaccine Development

Unmet Need

- Limited Local Capacities: Lack of domestic capabilities for clinical immunogenicity testing slows vaccine development.
- No GCLP-Certified Facilities: Absence of facilities certified by Good Clinical Laboratory Practice (GCLP) hinders regulatory approvals.
- Reliance on International Labs: Depen-dency on globally recognized KoLs or WHO reference labs increases costs and extends development timelines.

Capacity Created

Two GCLP certified facilities established for conducting validated assays to support immunogenicity assessment of candidate vaccines in clinical development

Two GCLP certified facilities established for conducting validated assays to support immunogenicity assessment of candidate vaccines in clinical development.

Interactive Research School for Health Affairs (IRSHA)

GCLP facility for clinical immunogenicity assessment of Dengue, Chikungunya and COVID-19 vaccines

Central Research Laboratory (CRL) at Kempegowda Institute of Medical Sciences (KIMS)

GCLP facility for clinical immunogenicity assessment for Pneumococcal vaccines

Overview of the Capacities Built in Shared Facilities for Vaccine Development

Interactive Research School for Health Affairs (IRSHA), Pune

Outcomes

- Cost Savings: Local testing reduces expenses by avoiding overseas outsourcing.
- Quick Turnaround: Faster results by conducting tests domestically.
- Regulatory Compliance: Approved testing data supports both national and international regulatory submissions.
- Skill Development: Enhances local expertise in immuno-genicity testing.
- High-Quality Facilities: World-class infrastructure for vaccine and antiviral evaluation.
- Global Collaboration: Positions India as a competitive player in the global biotech industry.

Assays/Services available

- Immunogenicity assessment for Dengue and Chikungunya vaccines in pipeline
- Cell based assays, serological assays, and quantitation of viremia
- Assay validation - as per ICH Guidelines
- 10 BSL2 and 01 BSL3 facility
- Dengue - PRNT for all serotypes, NS1 ELISA, IgM ELISA
- Chikungunya - IgG ELISA, IgG isotyping and PRNT50 assay
- SARS CoV2 Antiviral testing

Services Provided

More than 70 collaborations are in place with Indian and global industries

6 Major clients

SERUM INSTITUTE OF INDIA · Reliance LIFE SCIENCES · zydus Dedicated To Life · BHARAT BIOTECH · INDIAN IMMUNOLOGICALS LIMITED · Genova

7 SMEs

i-SERA Biological, Premium serums & vaccines; Bioklone Biotech; VINS Bio Products; Biological E, Kashiv Biosciences

4 Academic Partners

DRIVEN, AFI CMC, Pune knowledge cluster, Bharati Vidyapeeth Medical college

2 Global partners

IVI

1- Startup

SEAGULL BioSolutions Pvt. Ltd.

GCLP and NABL accredited

Demonstrating IRSHA capacities under NBM support

Kempegowda Institute of Medical Sciences (KIMS), Bengaluru

Outcomes

- 50-70% reduction in service time
- Reduced dependency on global service providers
- 50-60% reduction in service costs.
- Enhanced capability and infrastructure for GLP compliant assays
- Enhanced quality and regulatory compliance for clinical development

29 clients across academia, corporate hospital for bacterial ID/AST & serotyping

32 personaltrained in GCLP, SOP preparation, assays & LIMS training

Accreditations
NABL- ISO15189-2012; GCLP, DSIR, GFGP

Dedicated pneumococcal vaccine immunogenicity testing facility with MOPA, ELISA and Cell culture capacity

Services offered at CRL KIMS

- Pneumococcal Serotyping by Quellung test
- Archiving of Pneumococcal isolates
- Detection and serotyping of S. pneumoniae by Quantitative Multiplex Real Time PCR
- Bacterial culture, Identification and Antibiotic Sensitivity testing
- ELISA and OPA assay for Pneumococcal Vaccine immunogenicity testing
- Bacterial whole genome sequencing
- Qualitative detection of SARS – CoV-2 RNA using Real time PCR platform

State of Art GCLP compliant immunogenicity testing facility Capacity levered for COVID-19 vaccines

Two WHO reference laboratories at Alabama & London provided support for establishing MOPA & ELISA assays

Four BSL2 and one BSL3 laboratories established in this facility

Over the past four years, with the support of NBM-BIRAC, CRL, KIMS has established a cutting-edge dedicated facility in conjunction with WHO referral centres to effectively address existing gaps. The CRL facility at KIMS has emerged as a beacon of excellence, significantly impacting the accessibility and serves as a hub for prompt and cost-effective immunogenicity testing for Indian manufacturers. Affordability, a perennial concern in healthcare, has been directly influenced by the CRL facility's initiatives.

The collaborative efforts of NBM, BIRAC have empowered KIMS to conduct cost-effective research, leading to the development of assays that are not only of high quality and within the economic reach of an Indian academic and vaccine manufacturers. The model established by NBM, BIRAC and CRL, KIMS has set a benchmark for public-private partnerships, fostering an environment where industry stakeholders, academia, and government bodies work seamlessly toward shared goals.

CRL facility at KIMS, made possible through the visionary support of NBM, BIRAC, stands as a testament to what can be achieved when strategic investments are made in the intersection of research, innovation, and accessibility. Its impact on the Indian biopharma ecosystem is multifaceted, influencing affordability, and acceleration in ways that will undoubtedly shape the future of Vaccine development in our country. This facility serves as a shining example of the transformative power that collaborative efforts can have on advancing medical science and improving the lives of countless individuals.

Dr. K. L. Ravi Kumar
Chief Central Research Laboratory (CRL), KIMS

Shared Infrastructure

Strengthening to Support Biotherapeutic Development

Unmet Need

- Enhanced dependency on out-sourcing the manufacturing for preclinical and clinical development
- Limited capacity in India for early-stage manufacturing, end-to-end capacities from cell line develop-ment, process development to GMP manufacturing.
- Lack of existing manufacturing facilities in country for novel therapies like CAR-T. Dependencies on services outside country add to the out-of-pocket expenses for patient (INR 5-8 Crores.

Biologics Product Development Pathway and Infrastructure Required

Clone selection Clone characterizatn Media optimizatn Cell Line banking	**Process Development**	**Bio-Physicochemical Characterization**	**Preclinical studies cGMP Manufacturing**
Cell Line Repositories and Media Manufacturing Facilities	**Process Development Labs**	**GLP Analytical characterization Labs**	**cGMP Manufacturing**

cGMP Accredited Facility

Shilpa Biologicals Pvt Ltd, Dharwad, Karnataka

Outcome and Impact

Industry Impact

- Innovation: Cutting-edge R&D, collabo-rations spurring new therapies.
- Production: Increased capacity, cost efficiencies, meeting global demand.
- Regulatory: High compliance standards, global certifications (FDA, EMA).
- Market Dynamics: Competitive edge expanded domestic and international presence.
- Advancements: New biologics, biosimilars, personalized medicine, breakthroughs in key therapeutic areas.

Clients Served

LUPIN
Dr.Reddy's
Sputnik V
SUN PHARMA
SERUM INSTITUTE OF INDIA
Cipla

Assays/Services available-

Process and Analytical

- Clone development and characterization
- Process Development
- Fermentation (2L to 50L capacity)
- Batch, Fed batch and perfusion – micro/mammalian
- Scaleup & Scale down Model Establishment
- Viral Clearance, BET Removal & Resin usage establishment

Method development, qualification/ validation

Trainings conducted

1. Compliance and Quality
2. Safety and Environmental
3. Technical and Operational
4. Compliance and Regulatory

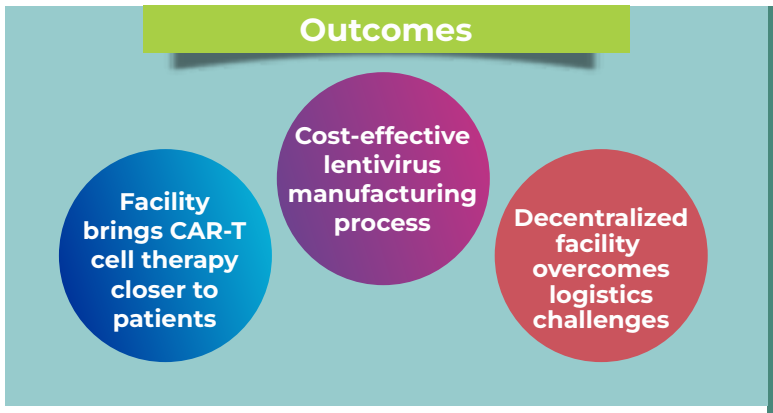
Local Impact

Facility is situated in remote location of Belur Industrial Area, Dharwad, Karnataka. NBM Supported led to following indirect impact-

- Employment: Job creation in research, manu-facturing, admin, and support.
- Economic Growth: Boosting local economy, supports ancillary industries.
- Infrastructure: Improved roads, utilities, and public



cGMP Accredited CAR-T and Lentivirus Manufacturing Facilities



TATA MEDICAL CENTER INTAS

CliniMACS Prodigy System at cGMP manufacturing facility at Tata Medical Centre Kolkata (Outsourcing partner of Intas)

Key Gaps and Needs potentially achieved by Technology

Automation & Standardization

Regulatory Compliance

Clinical Integration

Impact of CliniMACS Technology

- Integrated automated platform for cell processing and manufacturing
- Improve Consistency in product quality
- Enhance scalability with cell therapy production
- Streamline workflow

CAR-T Prominence

CAR-T cell therapy is a technological breakthrough for relapsed B cell lymphomas (B-NHL) and leukaemia (B-ALL) with a potential to revolutionize the treatment paradigm for cancer patients all over the world.

CAR-T Gaps and Challenges

- Lentivirus is a key component of CAR-T therapy, but its high cost makes CAR-T a very expensive therapy. It takes over almost 50% cost of the overall therapy

NBM support

- To produce affordable lentivirus, ultimately reducing the overall cost of CAR-T therapy and making it more accessible to the Indian population.
- Facility aims to facilitate the requirement of Lentivirus to other pharma companies, start- ups and academic institution working in the Cell therapy domain as there are very limited supply and availability of lentivirus in India.

Shared Infrastructure

Strengthening to Support Biotherapeutic Development

Unmet Need

- India's biosimilar market is rapidly expanding with many candidates in the pipeline.
- Biologics are complex molecules which need extensive characterization to ensure safety and efficacy
- Biotherapeutics characterization services are often inaccessible or unaffordable due to high capex investment which limits their access to SMEs and startups in India.
- Academic facilities unable to meet Global CRO standards for regulatory data submission

Capacity Created

GLP facility for Characterization and Validation of Biotherapeutics

Service facilities for advanced analytical characterizationeutics

Centre for Advanced Protein Studies (CAPS), Syngene

Expansion of existing capacities at Syngene

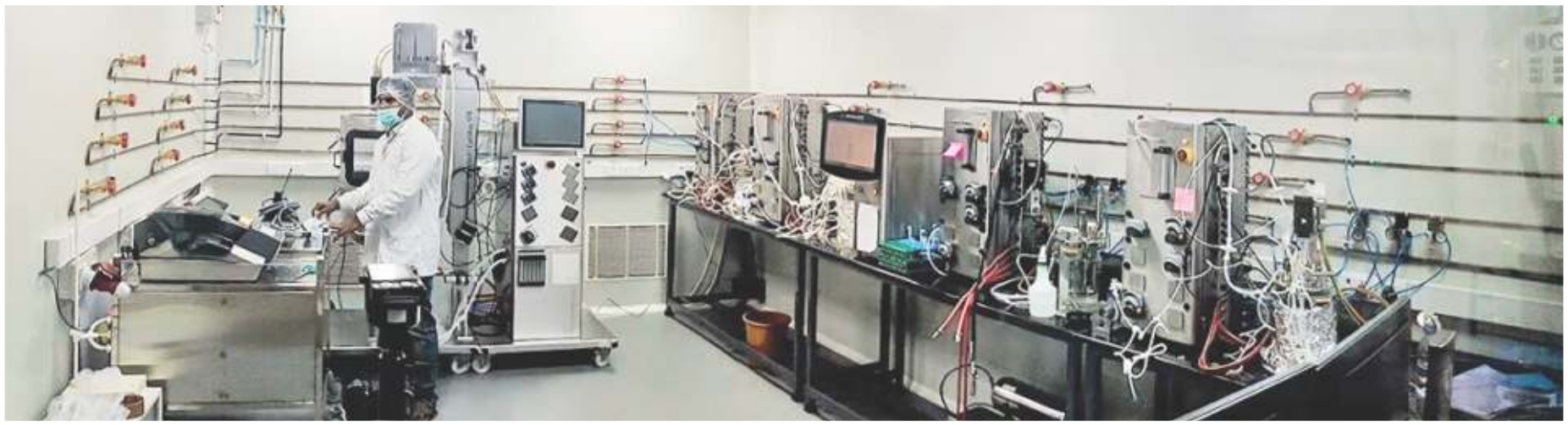
Cost-effective GLP compliant testing for start-ups, academia, and Industry.

CSIR-Indian Institute of Chemical Technology (CSIR-IICT)

Service facility for Analytical Characterization of biotherapeutics under GLP environment for regulatory compliance.

Centre for BioPharma Analysis, Entrepreneurship Development Centre (EDC)

Service facility for high quality in vitro bioanalytical characterization of biotherapeutics under GLP environment for regulatory compliance.



Overview of the Capacities Built in Shared Facilities to Support Biotherapeutic Development

Center for Advanced Protein Studies Syngene, Bengaluru

Outcomes

12 Clients

12 Technological Scopes

Assays/Services available

- Bioanalytical Protein studies accredited by National GLP Compliance Monitoring Authority.
- Protein analytical services on Q-ToF mass spectrometers, SEC MALS, CE, iCE, AUC, Biacore T200 and many other Instruments.
- MALS, HPLC/UPLC, Q-TOF Mass Spec, Surface plasmon Resonance, Analytical Ultracentrifuge, Capillary Electrophoresis, Imaged capillary isoelectric focusing (iCE), Endosafe-nexgen PTS.

Services Provided

- Large molecule quantification in blood, plasma, serum samples

Technical Scope of Clients Projects

- cIEF, SPR Analysis, SEC-MALS, Biocore T200, Mass Analysis, RP-HPLC, HPLC and Mass, HIAC, Flowcam, Glycan Analysis, LCMS, CE-SDS

Clients Feedback

"Appreciate for the quality of service provided to Orbicular. We sincerely appreciate your efficient, customer service, the level of detail and accountability you have demonstrated on the project. I will continue to recommend your services to other companies and contacts, we look forward to continuing this relationship."

-Dinesh Satone, Orbucular Pharmaceutical Technologies Pvt. Ltd.

Accreditation
GLP certification by NGCMA

Overview of the Capacities Built in Shared Facilities to Support Biotherapeutic Development

CSIR-Indian Institute of Chemical Technology (CSIR-IICT), Hyderabad

Outcomes

11 Trainings conducted on OCED documents

13 Clients availed services

Apicore
Center for API

Galaxy International Corp.
Edging Towards Success

ORBICULAR

Sandor
Speciality Diagnostics Pvt. Ltd.

aragen

NIRMA UNIVERSITY
INSTITUTE OF MANAGEMENT
NAAC ACCREDITED 'A' GRADE

Accreditation
GLP (applied), NABL

Assays/Services Available

- Physicochemical and structural characterization using different analytical techniques under GLP compliance laboratory
- Primary structure
- Secondary structure prediction
- Purity, impurity and charge variant analysis studies

Services Provided

- Multiple services for analytical assays
- Primary and higher order structures determination
- PMT, Molecular Mass determination
- Purity, impurities, contaminants determination assays
- Aggregation assays
- Stability study
- Charge variant analysis,
- Capillary isoelectric focusing

Plate Reader (MMR)

UNIFI software

Capillary Electrophoresis

Circular Dichroism Spectroscopy

Centre for BioPharma Analysis by Entrepreneurship Development Centre (EDC), Pune

Outcome and Impact

- One-stop solution for an array of the analytical assays.
- Supports startups, academia, and corporate organizations
- Supports analytical characterization in biosimilar development for faster patient access.
- Key achievements: facility leveraged for COVID vaccine and biosimilar data generation.
- Boosts employment by supporting BioPharma, startups, and BIRAC grantees.
- Trains students and employees, enhancing industry readiness and employability.
- Renowned as a supportive, professional, and non-profit partner for innovators.

Assays/Services available-Process and Analytical

- Primary structure
- Higher order structure
- Glycan analysis
- Aggregation analysis
- Impurity analysis
- Post translation modifications
- Functional assays
- Protein N-Glycan Analysis by HPLC
- Binding Kinetics Analysis
- ADCC Assay and CDC assay
- Protein N-Glycan Analysis by LCMS Mass

Trainings

Facility is conducting numerous trainings on GLP, Protein characterization, MTA, Regulatory Aspects of Biopharmaceuticals etc.

Clients found services to be affordable in comparison to global alternatives.

Affordable and discounted pricing for Academia and Startups

Centre for BioPharma Analysis by Entrepreneurship Development Centre (EDC) Client served (Industry, Academia, Start-ups)

Glimpse of established CBA-EDC Facility

The centre for BioPharma Analysis (CBA) is an initiative of Venture centre supported by the National BioPharma Mission, BIRAC (Government of India). The CBA is a well-resourced and specifically designed facility for carrying out cGLP workflows studies and experiments for biopharma characterization. CBA is an open access GLP compliant facility hosting dedicated high-end instrumentation and providing hand holding and advisory support to biopharma researchers.

In last 4 years, CBA has analysed 3000+ samples and has carried out 10+ Biosimilarity assessment projects for 30+ clients from Industry and Academia. Data generated at CBA has been successfully used by clients for regulatory filings. CBA offers special discounts to academia and startups. CBA as a resource centre has been instrumental in training 1000+ participants through its technical theoretical and hands on training programs.

Smita Kale, PhD
Advisor - Bioincubation
Entrepreneurship Development Center, Venture Center (Registered Trademark), Pune

I am writing to convey my gratitude for the excellent analytical services we have experienced from fast one and half year. VC analytical team is very knowledgeable and quick responsive. Throughout our sample analysis, they were courteous and helpful and went out of their way to ensure that all my needs were met with good deed. Appreciated all VC analytical teams

-Sudarshan Reddy, Founder & CEO, Oncosimis Biotech Pvt Ltd.

We are really pleased with Venture Centre's dependable and effective testing services; We greatly benefited from your knowledge, adaptability, and willingness to collaborate during our testing. The business process went smoothly from requirement assessment to test report submission. The laboratory's top-notch facilities with knowledgeable technical staff were truly remarkable. We want to keep working together on any upcoming projects that may be needed.

-Kondiparthi Chiranjeevi, General Manager, BYCUS THERAPEUTICS PRIVATE LIMITED.

I would like to extend my heartfelt gratitude for the meticulous organization and flawless execution of the four-day workshop on LCMS analysis for large molecules. Your team's exceptional planning and execution were truly commendable. Throughout the workshop, our team had the privilege of engaging with your esteemed scientists and experts. Their profound expertise and willingness to generously share their knowledge have immensely enriched our learning experience. We have acquired valuable insights and wealth of information relevant to LCMS analysis for large molecules. Once again, I wish to express my sincere appreciation for delivering an outstanding workshop. Your unwavering dedication to providing a comprehensive and engaging program is truly admirable I am grateful for the knowledge imparted and the networking opportunities facilitates during the workshop.

-Dr. Avinash Gaikwad, Head - Shimadzu Application Development centre

Shared Infrastructure

Strengthening to Support Biotherapeutic Development

Unmet Need

- Access to well characterized cell-lines is one of the prominent issues faced by manufacturers and entrepreneurs for developing biopharmaceuticals products.
- Lack of cGMP accredited cell line repository in India.
- Cell Line Procurement, Cell Bank storage and Cell bank characterization is completely outsourced.
- Cell lines for use in India either have to be ordered from cell banks, overseas (that have challenges like prohibitive shipping costs, time delays and customs issues); bought from companies (with high cost of licensing fees and royalties) or are sourced from other academic labs (risk of misidentification and purity).

Capacity Created

Cell Line Repositories

CSIR-Institute of Microbial Technology (NRGCBIO IMTECH), Chandigarh

The facility is established, commissioned and currently functional for production of cell banks.

National Centre for Cell Science

Mammalian Cell Line repository to provide following services:

- Procurement, Characterization and supply of microbial strains and vectors.
- Safe storage of cell banks
- Cell bank characterization as per ICH guidelines
- Distribution of characterized microbial cell lines to researchers and companies

Strengthening to Support Medical Devices and Diagnostics

Unmet Need

- Translating medical devices from discovery to development involves design iterations. This required physical prototypes fabricated using materials and processes intended for large-scale manufacturing.
- There are limited facilities in the country that offer these services at an affordable cost.
- e country to offer these serves at affordable costs

Medical Device Prototyping Facility

C-CAMP

Rapid prototyping facility for Microfluidic Medical devices, ISO 13485 accredited

Marathwada MedTech Lab, Netra Accelerator

Facility for rapid prototyping, and testing of medical devices, ISO 13485 accredited

Yenepoya University

State-of-the-art infrastructure for prototyping & establishing proof-of-concept, ISO 13485 accredited

IIT Kanpur

Facility to design and fabrication of medical devices and equipment, ISO 13485 accredited

Overview of the Capacities Built in Shared Facilities to Support Devices & Diagnostics Development

Centre for Cellular and Molecular Platforms (C-CAMP), Bengaluru

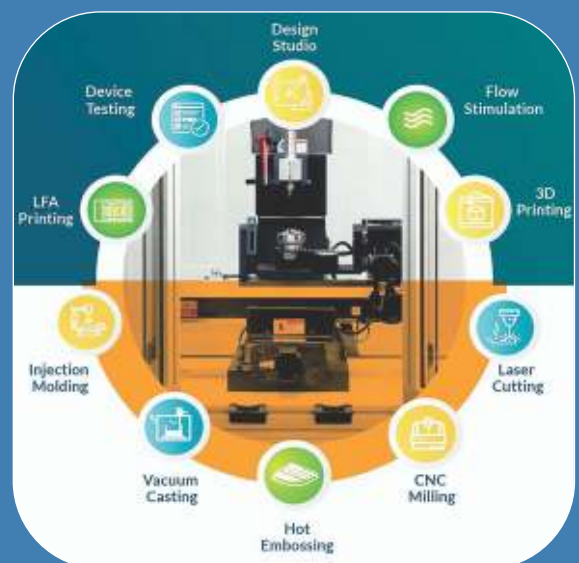
Outcomes

160 Projects successfully Serviced

~65 Clients served across SMEs, Academia & GoI Institutions, and Industry

Services available

1. Complete 2D & 3D designing, modelling & printing
2. Layout editor for microfluidic chip mask design.
3. Designing with CleWin, SolidWorks & Fusion 360 from simple to complex device designs.
4. Design iterations to improve aesthetics
5. Glass-based microfluidic medical devices service
6. 3D Bio-microfabrication for Therapeutics



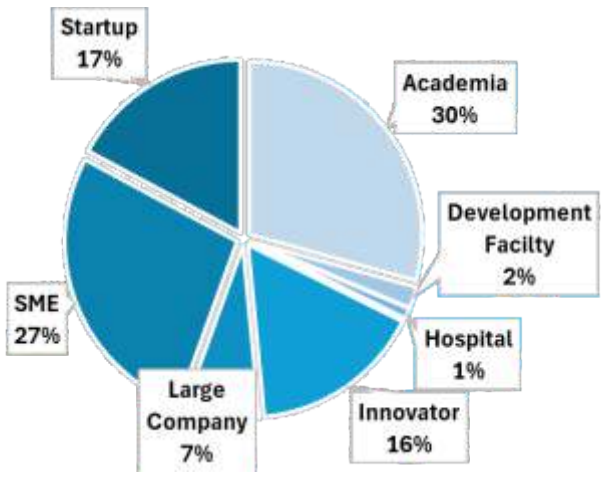
16+ Hands-on trainings and seminars organized




Shared Infrastructure

Netra Accelerator Foundation, Aurangabad

Output



Client's Distribution

Services: 9 types of services offered

Clientele: Over 100 SMEs, startups, and individual innovators.

Medical Devices: Worked on more than 60 medical devices in prototyping, designing, and assembly services.

Accreditation

ISO 13485 accredited

Assays/Services available

- Offer services for RPT with range of thermo plastics, metal, and electronics PCB.
- Industry grade thermoplastic 3 D printing
- Machining complex geometrical shapes
- PCB prototyping
- SMD devices mounting and soldering

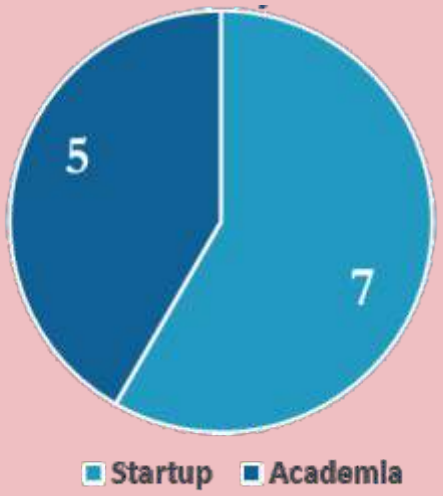
Training Conducted

1. CNC and VMC machining
2. 3D Printing
3. Electronics Designing
4. PCB Prototyping
5. 3D Scanning
6. Laser Cutting
7. Design Thinking

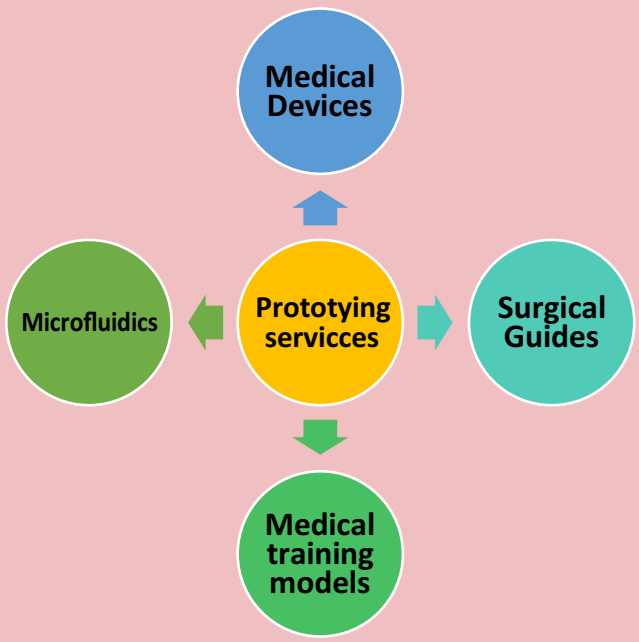
Shared Infrastructure

Yenepoya University, Prototyping Facility, Mangalore

Output



Distribution of Services



Assays/Services available

- Clinical Need Validation, Industrial Product Design, fabrication of thermoplastic, polymer and metal-based parts/products, Bioprinting/Tissue Engineering, PCB fabrication, Electronics Prototyping, Application Development and Product Validation
- 3D Printing, CNC Machining, Bioprinting, PCB Fabrication and Automated Assembly, Injection Moulding
- 3D printers available at the facility includes FDM, SLA, SLS and DMLS (Metal), along with high-end 3D scanners

Grantee's Voice

- NBM's funding and support provided a much-needed solution to create a conducive environment for innovation. Notably, NBM's approach emphasised accessibility, welcoming grantee and non-grantee startups to leverage the facility's resources.
- NBM's support extends beyond financial backing, encompassing strategic efforts to enhance the facility's accessibility and visibility.
- NBM's backing amplifies the facility's impact, reaching a broader spectrum of potential users.

-Yenepoya University Grantee

Shared Infrastructure

IIT Kanpur (Prototype) Facility

Outcomes

16
Services Offered

18
Clients served

16
Trainings conducted for 1200 candidates

~100
Companies visited IIT Kanpur facility

~22
Companies signed NDAs

Accreditation
ISO 13485 accredited

Services available	Clients
1. CNC Lathe	1. SiddLabs Pvt. Ltd.
2. CNC Vertical Milling	2. Eedha Innovations
3. CNC Vertical Milling S-Axis (Bench)	3. D IV Enterprises
4. LASER Cutting CO2 (35W)	4. Pinaka Technologies SG Pvt Ltd
5. EPLOG LASER Engraving M/C CO2 (J 50W)	5. Lenek Technologies Pvt. Ltd.
6. 3D Printer (FDM)	6. Innobody Systems
7. 3D Printer (SLS)	7. Joey Envirotech Pvt. Ltd
8. Vacuum Forming	8. Geo Informatics Consultants Pvt. Ltd.
9. EDM a) Wire, b) Drill, c) Die Sink	9. Edhaa Innovations Pvt. Ltd.
10. Water Jet Machine	10. Design Directions Pvt. Ltd.
11. Scanner	11. Pinaka Technologies S G Private Limited
12. Reverse Manufacturing	12. Ghost Vision Pvt Ltd
13. Composite Fabrication Area	13. Dimension Mechanix Pvt. Ltd.
14. Prototyping Design	14. CSIR-CISO
15. CAD	15. Morphedo Technologies Pvt. Ltd
16. PCB Design	16. Indian Veterinary Research Institute
	17. Adroitec Information Systems Pvt. Ltd.
	18. Kulwanti Hospitals



Strengthening to Support Medical Devices and Diagnostics

Unmet Need

- Electrical safety and electromagnetic disturbances testing are required for regulatory compliance
- Limited availability of such facilities in the country to offer these serves at affordable costs

Capacity Created

Electromagnetic interference (EMI) and electromagnetic compatibility (EMC)

IIT Kanpur

Facility for conducting electromagnetic interference and electrical safety tests required for various medical instruments and IVDs

SAMEER

EMI/EMC test facility and safety testing facility

Shared Infrastructure

IIT Kanpur (EMI) Facility

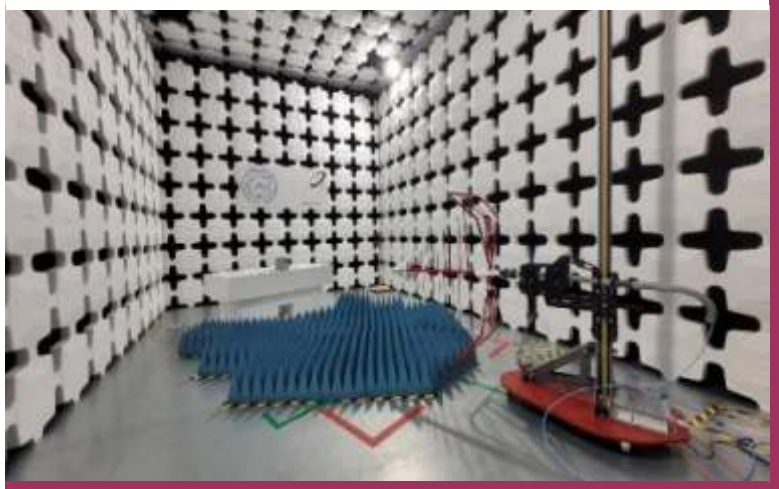
Impact of the Test Facility

- One of its kind facility in the country for affordable EMI/EMC testing of medical instruments.
- Crucial for start-ups and small-scale industries in medical electronics.
- National Support System- Supports medical industry and academia, adapting global standards to Indian conditions.
- 10 Trainings conducted.
- 4 clients being offered services

AROGYAM

airth

FIEXE
National Centre for Flexible Electronics



Accreditation
NABL

Assays/Services available

- Electrostatic discharge (ESD) immunity test
- Electrical fast transient/burst immunity test (EFT/B)
- Surge immunity test
- Voltage dips, short interruption, and voltage variation immunity test
- Power frequency magnetic field test
- Conducted immunity test through RF disturbance
- Harmonic current emission test
- Flicker emission test, Conducted emission test
- Radiated emission test, Radiated immunity test
- Dielectric strength test, Ground bond/continuity test
- Leakage currents test, Insulation resistance test
- Impact test, Drop test
- Mechanical hazard associated with surface, corner, and edges
- Ball pressure test, Legibility and durability of marking test
- Sound pressure level test, UV radiation test
- Clearance and creepage distance test
- Cord anchorage and cord guard test
- Flammability test
- Humidity preconditioning treatment test
- Dry heat oven treatment test

Ecosystem Strengthening to Support Medical Devices and Diagnostics Development

Unmet Need

- Medical devices need to be tested through genotoxicity studies, general toxicology, and implantation studies in a GLP compliant lab for regulatory submission.
- Lack of large animal model facility for medical devices testing in the country

Capacity Created

Biological & Preclinical Testing

Palamur Biosciences Pvt. Ltd.

Large animal Testing facility for medical devices, ISO 17025 and OECD GLP accredited

one of its kind facility in india

Shared Infrastructure

Overview of the Capacities Built in Shared Facilities to Support Devices & Diagnostics Development

Palamur Biosciences, Large Animal testing facility, Telangana

Impact of the Test Facility

Services Provided

- 8 clients (4 Industry, 4 Start-ups, 1 CRO)
- Muscle/bone implantation studies in Dogs and Rabbits
- Extracorporeal Membrane Oxygenation (ECMO) pump studies in Sheep
- Catheter thrombo-genecity studies in Swine
- Coronary and peripheral Stent Implantation studies in Swine
- Wound dressing safety and performance evaluation studies in swine.

Meril
More to Life

Boston Scientific
Advancing science for life™

Vivo Bio Tech Ltd.
Your Drug Discovery Partner

Accreditation
NABL ISO 17025, CDSCO, and GLP

Assays/Services available

Biological and Preclinical Testing Facility for Medical Implants, Devices and Drug Device combinations for large animals such as Beagle Dog, Swine and Sheep with. Capacities for:

- Biocompatibility study (full battery of tests for medical devices)
- Preclinical safety and Performance evaluation studies for medical devices
- In-vitro cytotoxicity tests
- Genotoxicity in-vitro tests
- In-vitro hemocompatibility tests
- Histopathological evaluation
- Irritation and skin sensitization

The facility for safety evaluation of medical devices in large animal models meet international GLP standards.

BIRAC-funded institutions receive discounts, & clients benefit from timely, cost-effective studies compared to US and European CRO.

Changing Course

Establishing Robust Clinical Trial Networks across India

Message From Scientific Advisory Group For Clinical Trials Network, Co-Chairs

Dr. Sanjay Mehendale
Director Research at PD Hinduja Hospital and Medical Research centre

Dr. C S Pramesh,
Director at Tata Memorial Hospital Mumbai, Maharashtra, India

On behalf of the Members of the Scientific Advisory Group of the Clinical Trials Network of the National Biopharma Mission of BIRAC, Department of Biotechnology, Government of India: We have great pleasure in writing this brief note for the "Impact Book of NBM."

We would like to congratulate the leadership of the National Biopharma Mission for conceptualizing the idea of establishing networks of community- and hospital-based clinical trial sites in different parts of India. We strongly believe that these networks will complement the ICMR network of Clinical trial sites in India. It was indeed remarkable that although some NBM initiatives focused on strengthening the existing clinical trial sites, additional efforts were taken to create new clinical trial sites – this has gone a long way in scaling up research capacity and taking research beyond the "elite" institutions. It is heartening to note that a national-level platform involving clinical trial sites at institutions of repute and eminence located in different parts of the country has been created.

The SAG of Clinical Trials Network of NBM feels proud to be a part of this vital development over the last five years. This diverse group has provided critical input and direction to the sites to standardise operations, rationalise budgets, and improve the structure and functions of the participating sites. Although the sites faced serious challenges and hardships due to the COVID-19 pandemic, the NBM Secretariat worked diligently and supported all the clinical trial sites through difficult times. The capacity building, training, and monitoring provided by CDSA have also been noteworthy.

The Clinical Trials Network of NBM is a major national resource supporting 36 hospital sites (5 networks) and 11 community sites to undertake field- and hospital-based clinical trials. All the trial teams have been trained in ethics, clinical procedures [including screening, enrolment, follow-up, and retention], fieldwork, laboratory practices, and data management. They have already started participating in investigator-initiated and industry-sponsored clinical research studies. They are making efforts to position themselves as strong, vibrant, capable, and efficient groups to carry out Phase I, II, III, and IV clinical trials.

We would like to take this opportunity to congratulate the National Biopharma Mission on its extraordinary vision and foresight in setting up these networks.

Shared Infrastructure

Infrastructure Strengthening to Support Vaccine Development

Need

- There are 4 Dengue and 1 Chikungunya vaccine candidate in pipeline, and late-stage clinical development of these critical vaccines would require 12-15 established sites across geographies with mapped epidemiological data including incidence, prevalence and infrastructure for conduct of clinical trials

- There is lack of community-based sites in India for conduct of late-stage efficacy trials for commercialization.

Capacity Created

Clinical Trial Network

Strengthening field-based clinical trial capabilities for late-stage vaccine efficacy trials of prioritized disease – Dengue, Chikungunya and COVID-19

At existing DSS/DHS/DDESS site(s)

Study epidemiology of Dengue & Chikungunya in different age-groups

Prepare the sites for conduct of GCP compliant, field-based clinical trials

New DSS/DHS/DDESS

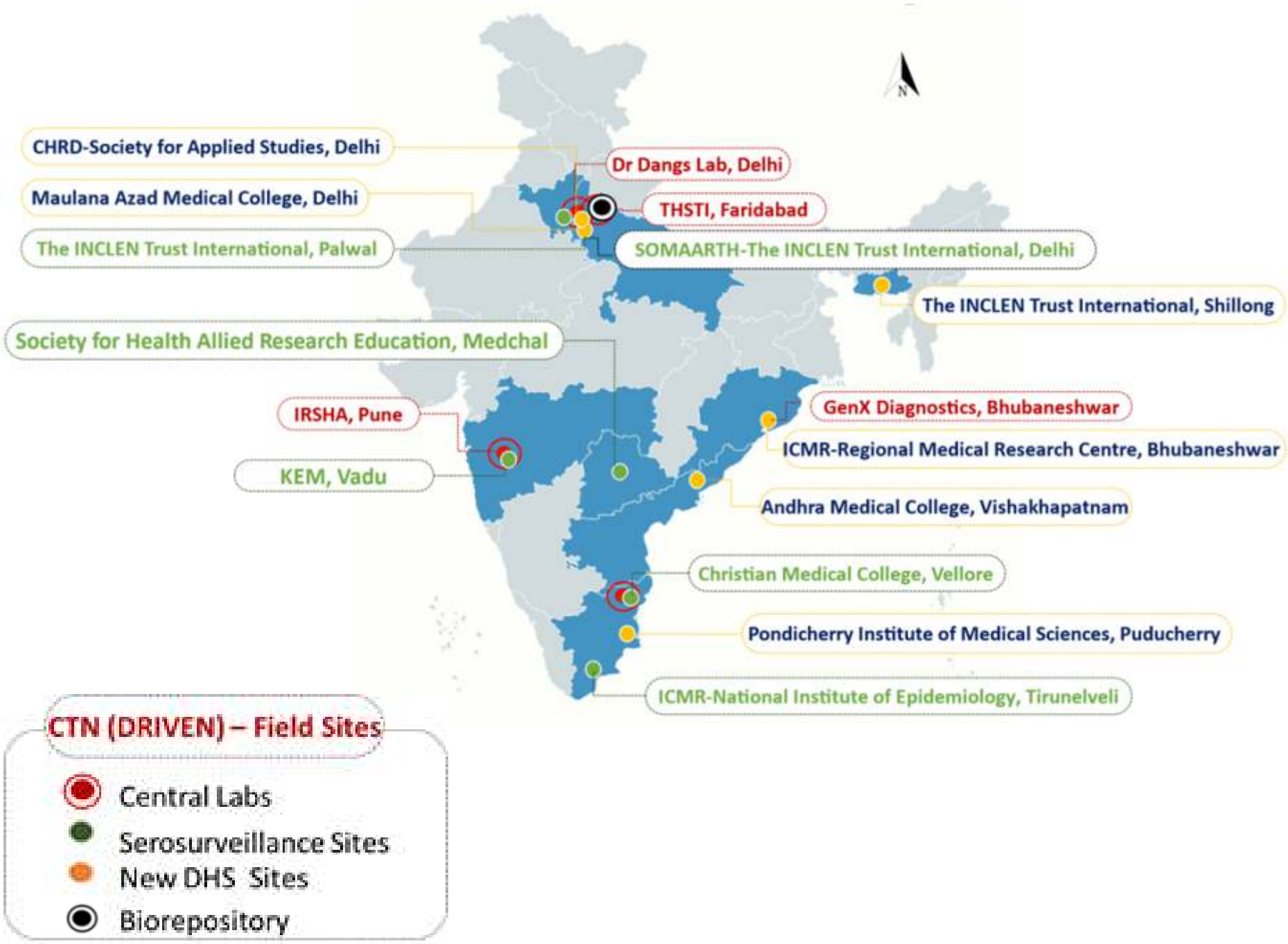
New sites to study epidemiology of Dengue & Chikungunya in different age-groups

Data Management Platform

Electronic data management was done through establishing SOMAARTH platform Within the network, for collecting, reporting, analysing and archival of community-based demographic, development, and environmental surveillance data (paperless e-data) across sites.

DRIVEN

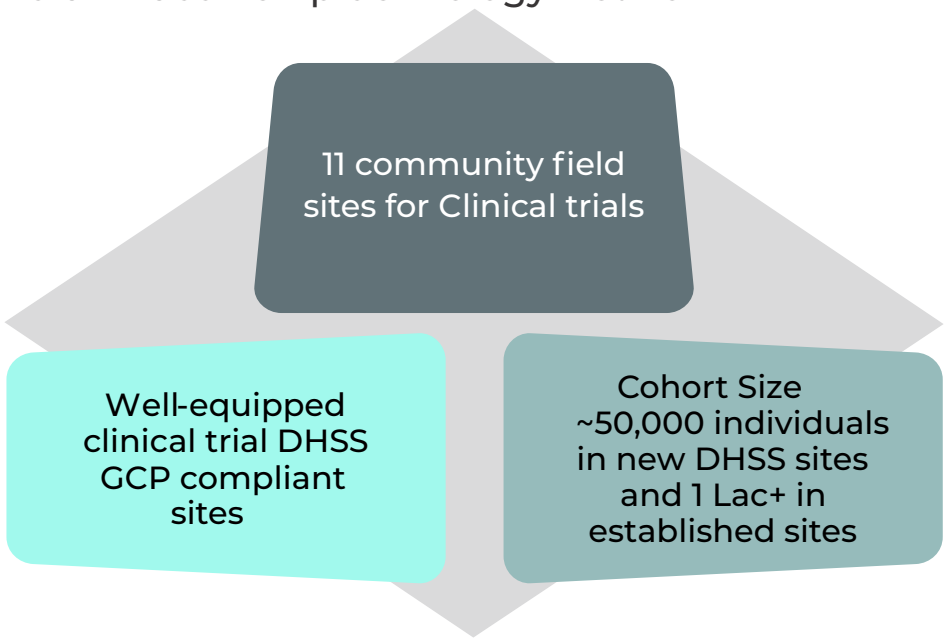
DBT's Resource of Indian Vaccine Epidemiology Network



DRIVEN

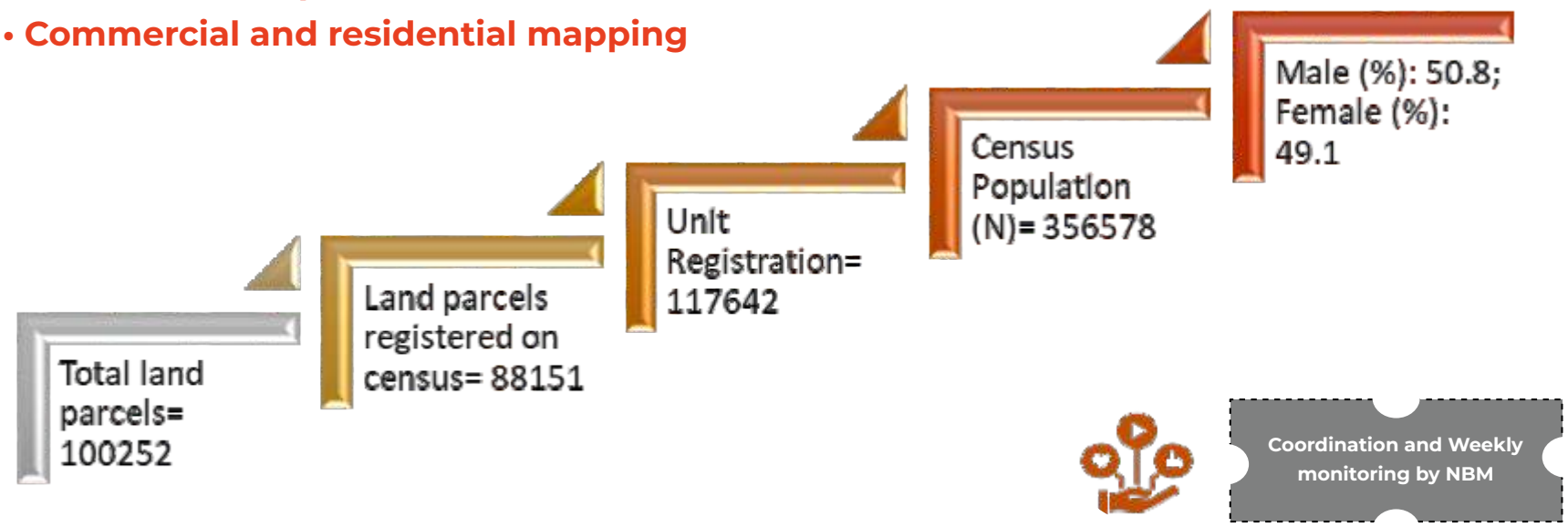
DBT's **R**esource of **I**ndian **V**accine **E**pidemiology **N**etwork

- **11** Sites in different geographic locations spread across India
- **11** Sites prepared for GCP and GDP skills
- **5** Conducted sero-epidemiological studies on SARS-CoV-2, Dengue, and Chikungunya in healthy cohort
- **6** New DHSS sites covering 50,000+ individuals at each site
- **11** Sites with healthy volunteer's database captured through SOMAARTH e-platform



Highlights

- **>3.5 Lac Census Population**
- **Geo Tagged**
- **Environmental parameters**
- **Commercial and residential mapping**



DRIVEN

DBT's **R**esource of **I**ndian **V**accine **E**pidemiology **N**etwork

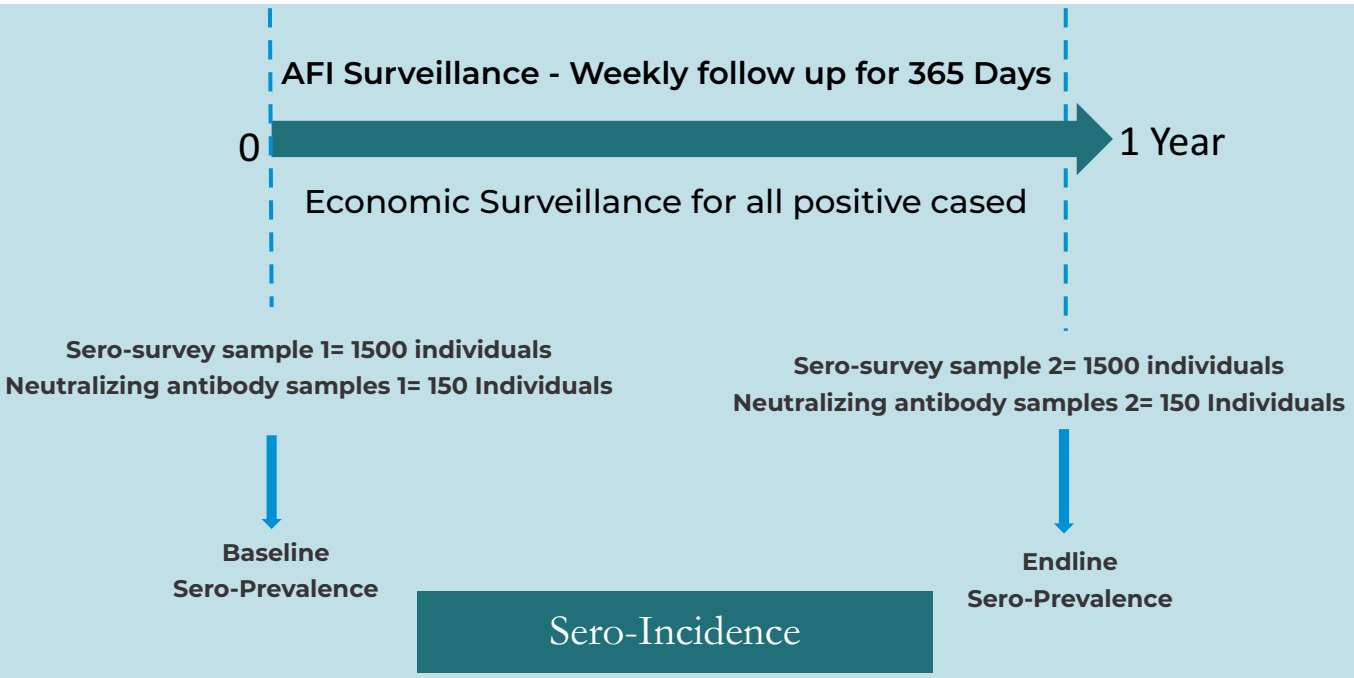
Strengthening Vaccine Clinical Trial Capacity

Community based surveillance to estimate seroprevalence and incidence of acute febrile illness (AFI) in India with focus on Dengue and Chikungunya- A prospective population-based multi-centric cohort study

6 Objectives: A prospective population based multicentric cohort study

1. Cohort establishment
2. Base line sero-prevalence of IgG, IgM and Neutralizing antibodies
3. Incidence of AFI including lab confirmed dengue and chikungunya
4. Etiology of other AFI infections
5. Incidence of asymptomatic & subclinical dengue and chikungunya infections
6. Spatiotemporal trend of occurrence of dengue and chikunguny

AFI Study Design



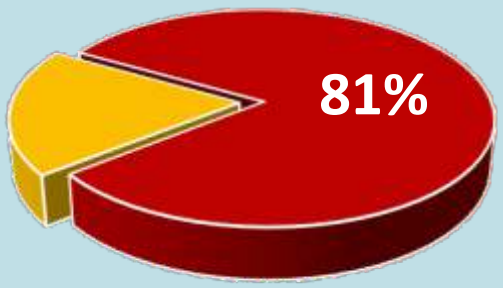
Each for dengue and chikungunya

sampling method: Each site divided into 5 clusters of 3-5 villages or census enumeration block or lance. Age stratified 1-2 individuals per household selected

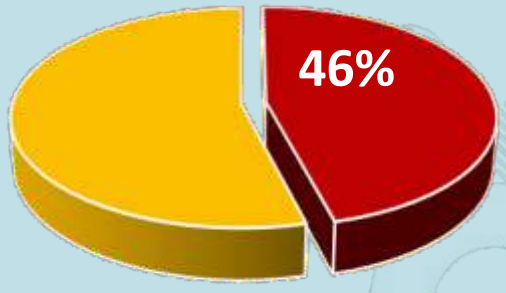
Overview – AFI Surveillance

Call & visit (home/hospital)	Acute phase- **SAMPLE A** (within 3- 7 days after onset of fever)	• Clinical assessment • Investigations for patient care- Rapid tests (Malaria and Dengue) • Dengue and chikungunya specific investigations • Referral
Follow up visit (Home / hospital)	Follow up – Sample B (10 ± 2 days after onset of fever)	• History based assessment • Typhoid, Leptospirosis, Scrub Typhus specific investigation* • Referral **Only if fever persists*
Call & visit (home/hospital)	3rd follow up-**SAMPLE C** (preferably 21 ± 2 days after onset of fever)	• Clinical assessment • Dengue and chikungunya specific investigations • Referral

Dengue Seropositivity at baseline



Chikungunya Seropositivity at baseline

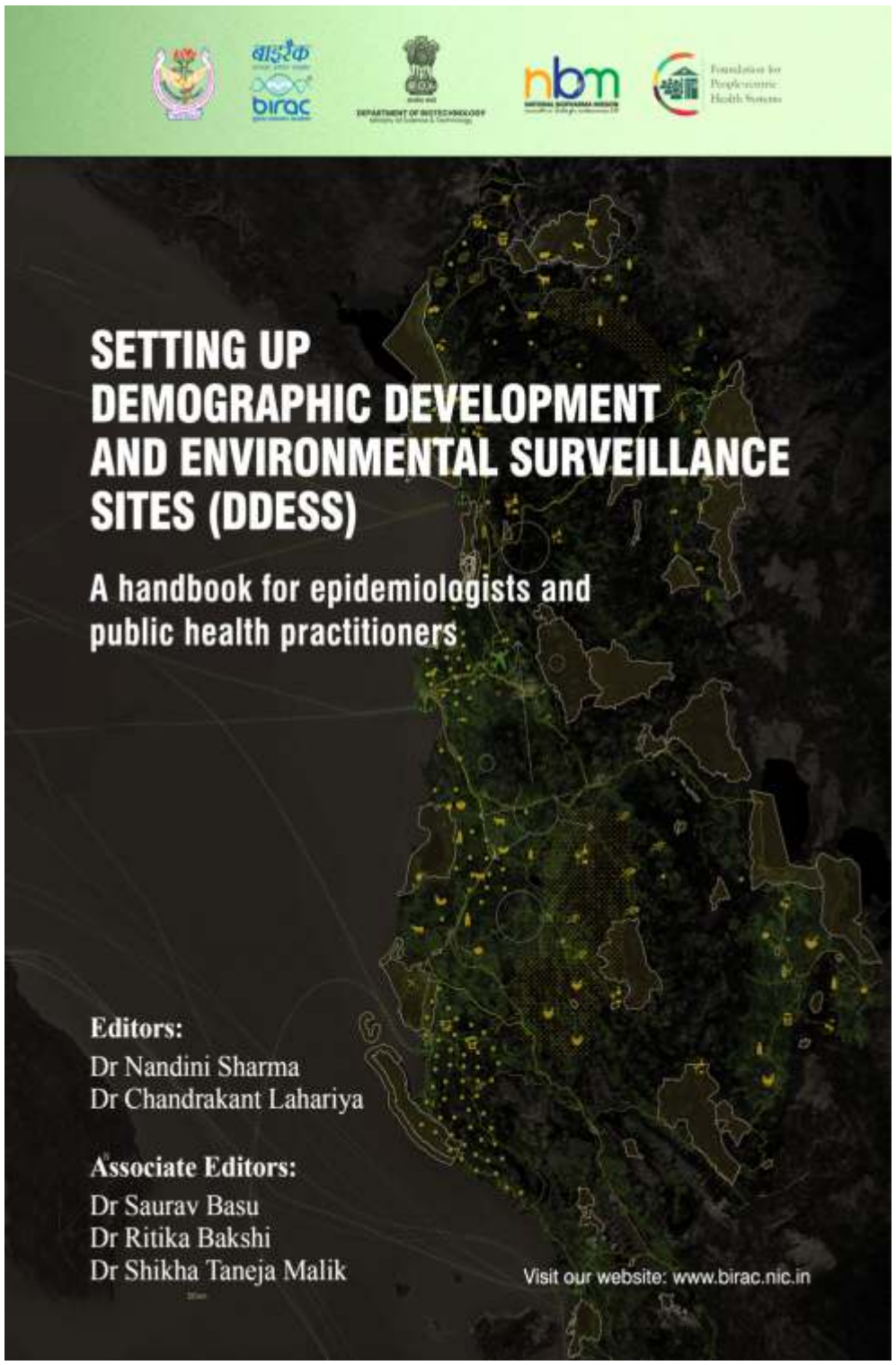


The study is ongoing across the DRIVEN network

Published Monograph on "Setting up Demographic Development and Environmental Surveillance Sites (DDESS)

NBM has supported the establishment of six new Demographic, Development and Environmental Surveillance Sites (DDESS) across the country as a part of the DBT's Resource of Indian Vaccine Epidemiology Network (DRIVEN). This monograph describes setting up of a DDESS site by Maulana Azad Medical College as one of the sites of DRIVEN. This comprehensive compilation covers the entire spectrum of DDESS, from their design and establishment to the generation of actionable findings. Demographic, Health and Environmental features are geo-mapped at these sites. This also shares the methodologies and various challenges faced during site development, including GIS mapping, ethical considerations, data collection methodologies, and ensuring the engagement and participation of local communities. Although, the title of this book contextualizes it to New Delhi-India, but the contents relates to and is relevant to many other parts of the country, cultural settings, and health care situations.

As Medical Colleges in India adopt an urban low socioeconomic area and provide comprehensive health services along with training graduates, post graduates and facilitating research, we plan to share this monograph with all the medical colleges (more than 700) across the country for the establishment of such sites by medical institutions which would help in collecting comprehensive data on population demographics, health outcomes, and environmental factors that can impact public health.



At Pondicherry Institute of Medical Sciences (PIMS), our experience in working as part of the DRIVEN Clinical Trial Network has helped in getting us onboard with other Institutions/organisations working on common protocols. This has been a new experience as earlier we were working/doing community-based projects focusing on local issues; however this network has broadened our horizons, we continue to learn and grow from the network about working with teams and experts who have been guiding and providing valuable advice on issues and processes which enabled us to efficiently meet the objectives of the project. The cohort of 54,000 individuals based in the community could be established only with the support of this network. The awareness regarding acute febrile illness, the symptoms, signs including prevention of Dengue and Chikungunya has increased in the study population.

The study participants/population developed through the DRIVEN network have benefitted by the regular house to house visits where individuals and families have been assessed for extending basic health care services including blood pressure examination. Several families have been referred for appropriate follow-up at primary, secondary and tertiary health care centres. The clinicians have had the opportunity to directly communicate with the families and provide health education to them. The individuals and families in the cohort have been an active part of our lessons on community engagement,

Dr. Anil Jacob Purty MD, DNB, MNAMS, PGDBE
Professor of Community Medicine,
Director -Principal, Pondicherry Institute of Medical Sciences
(A Unit of Madras Medical Mission)

Shared Infrastructure

Infrastructure Strengthening to Support Biotherapeutic Development

Unmet Need

- Increase in biosimilars and novel biotherapeutics in pipeline – nearly 10-15 products would need to be tested per year
- Limited capacity and centralized mechanism of patient recruitment and site onboarding within hospitals
- Individual hospitals recruited during trials – lack of harmonization leading to delays in clinical trials
- Lack of GCP trained manpower and well-equipped clinical trial sites act as a major bottleneck causing delay in the clinical trials.
- CT network of hospitals in four areas, i.e., Diabetology, Ophthalmology, Rheumatology & Oncology needs to be established with multiple sites accessible to Indian biopharmaceutical companies for conduct of clinical trials for Biosimilars/ Biologicals development.

Capacity Created

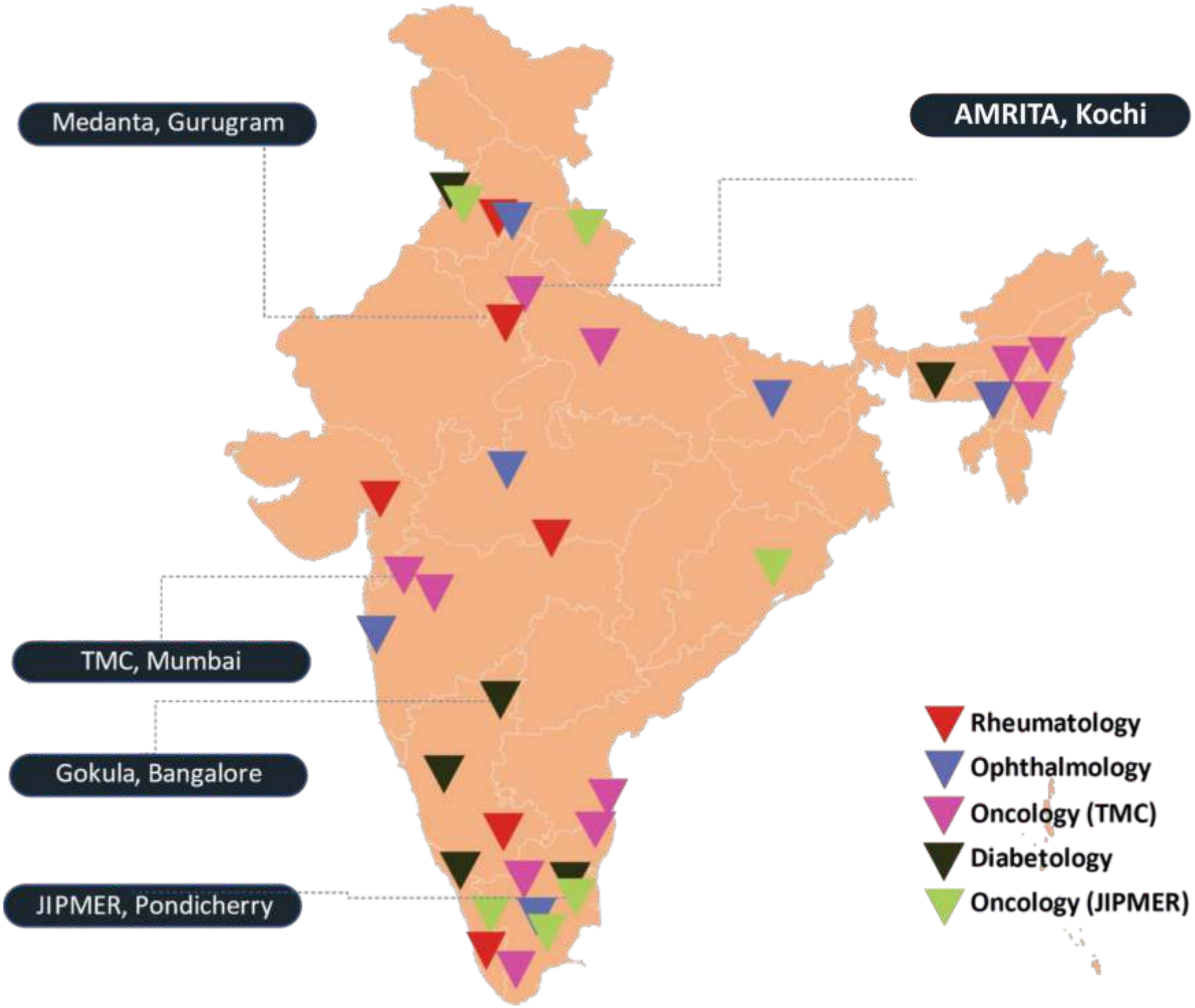
Clinical Network for Hospital-based trial in specialties of Oncology, Ophthalmology, Rheumatology and Diabetology

5 Networks established:

- Oncology- TATA Memorial Centre (TMC) led (11 hospitals)
- Oncology – JIPMER led (6 hospitals)
- Ophthalmology (6 hospitals)
- Rheumatology (7 hospitals)
- Diabetology (7 hospitals)

Year wise strategies

A PAN India Consortia of Hospitals in the Areas of Oncology, Ophthalmology, Rheumatology and Diabetology



INTERVENTION through NBM Support

- Supported well established basic infrastructure for conduct of clinical trials
- Access to well defined and characterized patient population
- Developed capabilities in terms of Skilled workforce and research team
- Enabled access to technical know-how to design and conduct clinical trials and harmonize across sites

CAPACITIES ESTABLISHED

- Developed Pan India Registry with prospective data collection of on a secure electronic database.
- In-depth information on treatment patterns and outcomes - including molecular subtype level t.
- Well-equipped sites to conduct ICH-GCP Clinical Trial
- CDSCO & DHR Registered Ethics Committees ready for CHOORD related biotherapeutics in India

The networks can be accessed by start-ups, Industry and academic institutions looking out for sites for clinical trials through BIRAC by writing to nbm1.birac@nic.in or technical.birac@nic.in. The site details will be shared as per requirement.

Network of Oncology Clinical Trials – led by JIPMER with 5 more Institutes

Network of Oncology Clinical Trials in India (NOCI) is a network of cancer centres established in 2020. The network brings together 6 large oncology centres representing different regions of India. The aims of this collaboration were the conduct of multi-centre clinical trials in cancer as well as to establish a registry of common cancer with representative data from different parts of the country.

IMPACT

Two sites, CMC Ludhiana and Amala Cancer Hospital with no prior experience in clinical trial are now conducting sponsored trials

A collaborative trial initiated by all 6 centres in breast cancer. There are currently 20 ongoing sponsored clinical trials. The network also selected for ICMR NCG randomized trial

CAPACITIES ESTABLISHED

- **Registry of cancers**

  Established multicentric cancer Registry data on 5 cancers with a total of over 4000 patient data.

Publications and Conference Abstracts from NOCI registry:

CC BY-NC-ND 4.0 · South Asian J Cancer 2024; 13(02): 142-145
DOI: 10.1055/s-0043-1771275

Original Article
Adolescent and Young Adult Cancer

Adolescent and Young Adults with Gastric Cancer (AYA-GC)—The Dilemma of an Under-Represented Group: A Multi-Institutional Analysis from the Indian Subcontinent

Soumya Surath Panda, Swati Sucharita Mohanty, Antara Sanyal, Prasanth Ganesan, Smita Kayal, Krishnakumar Rathnam, S. V. Saju, Sunu Cyriac, P. Unnikrishnan, Amit Sehrawat, Deepak Sundriyal, Ashwin Oommen Philips, Deepak Jain, Sumit Subhadarshi Mohanty, Sunil Kumar Agrawal, Lalatendu Moharana, Satyaprakash Ray Choudhury, Biswajit Dubashi

CC BY-NC-ND 4.0 · South Asian J Cancer
DOI: 10.1055/s-0044-1785460

Original Article

A Multicenter Study on the Challenges and Real-World Utilization of Immune Checkpoint Inhibitors in Resource-Constrained Settings: Insights and Implications from India

Ashwin Oommen Philips, Sunu Cyriac, P. Unnikrishnan, Anil T. Jose, Krishnakumar Rathnam, S.V. Saju, Smita Kayal, Soumya Surath Panda, Lalatendu Moharana, Sindhu Kilaru, Amit Sehrawat, Deepak Sundriyal, Puneet Dhamija, Deepak Jain, Pamela Alice K., Jaineet Sachdeva, Nishant Batta, Raman Arora, Yogesh Arora, Harpreet Singh, Hridui Anand, Ishu Sharma, Prasanth Ganesan

ABSTRACT | VOLUME 33, SUPPLEMENT 9, S1596, NOVEMBER 2022

382P Real-world data on treatment outcome of ALK positive non-small cell lung cancer from an Indian multi-centric cancer registry

S.S. Panda • L. Moharana • G. Biswas • P.K. Panda • S.K. Mishra • J. Pattnaik • S.P. Devaraj • S. Mohanty • S. Karunanidhi • S.L. Singuluri • S.V. Saju • A. Sehrawat • S. Mudgal • G.C. Subudhi • K.K. Rathnam • S.L. Cyriac • A.O. Philips • A.T. Jose • P. Ganesan • Show less

Open Archive • DOI: https://doi.org/10.1016/j.annonc.2022.10.419

CC BY 4.0 · Indian J Med Paediatr Oncol
DOI: 10.1055/s-0044-1779275

Original Article

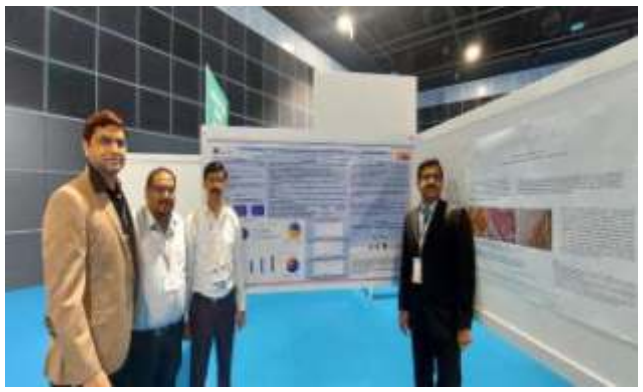
Real-World Experiences of Next-Generation Sequencing in Oncology: From an Indian Multicenter Registry and Collaborative Centers

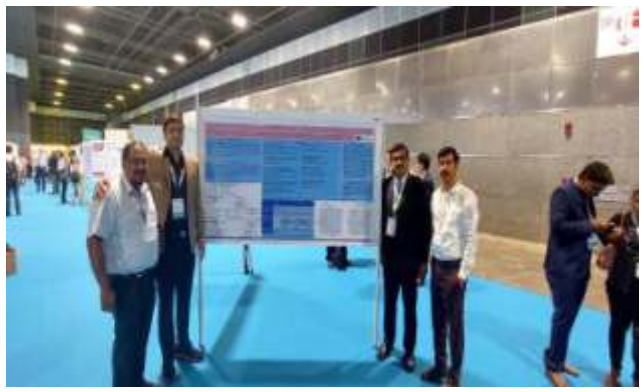
Ashwin Oommen Philips, Soumya Surath Panda, Sunu Cyriac, Lalatendu Moharana, Sindhu Kilaru, Spoorty Kolluri, Krishnakumar Rathnam, S.V. Saju, Honey Susan Raju, Smita Kayal, Dubashi Biswajit, Amit Sehrawat, Deepak Sundriyal, Anil T. Jose, Sreeja Raju, Preethi Paul, Prasanth Ganesan

Original Reports | Gastrointestinal Cancer

Clinicopathologic Profile and Treatment Outcomes of Colorectal Cancer in Young Adults: A Multicenter Study From India

Amit Sehrawat, MD, MBBS, DrNB; Mridul Khanna, MD; Smita Kayal, MD, DM; Deepak Sundriyal, MD, DrNB; Shraddha Tiwari, PharmD; Sunu Cyriac, DM; Praveen Ravishankaran, MS; Jomon Raphael, MD, DM; Dominic Mathew, MS; Soumya Surath Panda, MD, DM; Lalhendu Moharana, MD, DM; Sumit Subhadarshi Mohanty, MS; Swati Sucharita Mohanty, PhD; Ashwin Philips, DM; Deepak Jain, MS; Pamela Jeyaraj, MD; Parvez Haque David, MS; Jaineet Patil, MD; S.V. Saju, DM; Krishnakumar Rathnam, MD, DM; Neha Sharma, MSc; Kaaviya Dheva, BSc; Sree Rekha Jinkala, MD; Kalyanasaran Raja, MS, MCh; Prasanth Perumadu, MS; and Prasanth Ganesan, MD, DM





NOCI Team presenting their data in various national and international conferences.

SUSTAINABILITY

With funding from participation in several national collaborative trials with multiple other groups, grant from ICMR-NCG for network mode trial, investigator's trial on Scalp cooling trial to prevent chemo induced alopecia, a device developed by BIRAC funded start-up, the network is well poised to self-sustain beyond the Mission's support

Testimonial:

Dear NBM team,

We are extremely happy to inform that 2 projects from NOCI submitted to the recent ICMR-NCG randomised trials project has been approved.

1. An RCT on S/L Buprenorphine vs Oral Tramadol in cancer pain

2. Intraperitoneal chemo in ovarian cancer.

Out of 156 applicants, initially 22 were short listed, where our 4 proposals were there. In the final approved 9 projects, 2 are from NOCI network.

We thank all the supports from NBM and CDSA team in mentoring and guiding us to this achievement. Hope for more such achievements in the future as a team

Dr Amit Sehrawat, Professor, AIIMS Rishikesh

Acknowledgement in published article

"The authors express gratitude to their sponsor, the Biotechnology Industry Research Assistance Council (BIRAC) team, for their crucial financial support and continuous guidance throughout the study. Additionally, the authors extend their acknowledgment to Dr Madhvi Rao for her administrative support and Ms Sathya N for contributions to the biostatistical analysis.

The Tata Memorial Hospital, leads another big oncology network of 11 centres.

IMPACT:

- BIRAC NCG-CTN have signed an MSA with Labcorp to expedite multicentric pharmaceutical trials and is in process of getting trials from Cipla and IQVIA. The same will be extended to other sites.
- Some of the outputs like SOPs, training modules, database development and guidance through NCG CRO would remain accessible to all the sites as per the need and do not require any financial support.
- Patient awareness activities are being conducted at all BIRAC- CTN Centers through pamphlet distribution.

All network sites are included in Oesophageal cancer trial funded by

ICMR INDIAN COUNCIL OF MEDICAL RESEARCH

MoUs

NOVARTIS

CAPACITIES ESTABLISHED

Registry: The network has developed registries for Lung cancer, Breast cancer, Colorectal cancer, Gallbladder cancer, Lymphomas and Chronic Myeloid Leukaemia with about 39,000 patient data.

Over 150 feasibility assessments have been received and shared with the respective pharmaceutical companies, of which 21 have been converted into trials.

NEIGRIHMS

HOMI BHABHA CANCER HOSPITAL, VARANASI

REGIONAL CANCER CENTRE THIRUVANANTHAPURAM

TATA MEMORIAL CENTRE SERVICE RESEARCH EDUCATION

MALABAR CANCER CENTRE THALASSERY

CACHAR CANCER HOSPITAL & RESEARCH CENTRE

MAX Healthcare

CANCER INSTITUTE (WIA)

Network of Rheumatology – Led by Medanta Institute of Education and Research (MIER), with 5 Leading Private/Public Hospitals and Rheumatology centres

The aim is to create a network of Rheumatology centres and research institutes across India with the mandate of establishing uniform research standards in compliance with best practices to ensure faster, cost-effective drug development in Rheumatology.

IMPACT

- Network established a registry of rheumatology diseases, followed by its Ethics Committee approval at all sites and enrolled 13444 subjects.
- Currently, 24 Sponsored studies and 03 Investigator Initiated studies are ongoing at sites.
  - 02 new centres of Rheumatology established under this project
- Publication- Conventional synthetic disease-modifying drugs (DMARDs) remain the mainstay of therapy of rheumatoid arthritis in India" - A cross-sectional study of a multi-centric observational cohort of Rheumatoid Arthritis patients, across rheumatology clinics at six centres across India.

CAPACITIES ESTABLISHED

- Registry of various Rheumatology diseases such as Rheumatoid Arthritis, Psoriatic Arthritis, Spondylarthritis, Myositis, Sjogren's syndrome, Systemic lupus erythematosus, Systemic sclerosis, ANCA associated vasculitis and Aortoarteritis. The 6 leading institutions have enrolled 12,339 subjects in various rheumatology diseases

OUTREACH EFFORTS

Diabetology network is led by M.S. Ramaiah Medical College and Hospitals, Bangalore with 7 sites across India with expertise in handling diabetes trials.

The uniformity is maintained across the sites by trainings, SOPs, access to technology's and regulatory & GCP compliance with the aim to make all the network centres world class stature in terms of research and training.

CAPACITIES ESTABLISHED

Registry: Diabetes registry has a total of 25276 patients data including type 2 diabetes mellitus and type 1 diabetes mellitus patients enrolled across different geographical locations in India.

IMPACT

- Clinical Trials: 2 MoUs signed with Pfizer and Paraxel. 11 feasibility studies.
- There are 13 clinical trials in total being conducted at the network sites
- 2 network sites NEIGRIHMS and SRM Chennai are new sites established trial units under this project
- PUBLICATION: Metabolism -Financial Impact of Diabetes Mellitus Treatment on Indian Patients" Indian Journal of Endocrinology.

Pfizer ⟵ MoUs ⟶ novo nordisk®

OUTREACH:

Dr. Pramila Kalra, presented about CTN Diabetology at Indian Society for Clinical Research, 16th Annual Conference 2023, 23rd- 25th February 2023 New Delhi Demystifying Innovations in Clinical Research (Innovation. Responsibility. Humanism)

Abstract on topic **“Hospital Based Multi Centric Diabetic Registry Data”** presented at **NAMSCON 2023**, 63rd Annual Conference of National Academy of Medical Science

Abstract on topic **“Hospital Based Multi Centric Diabetic Registry from India”** submitted to **ICE 2024**, 21st International Congress of Endocrinology

Network of Ophthalmology – Led by Amrita Institute of Medical Sciences and Research Centre, Kochi, Kerala, with 5 more Institutes.

CAPACITIES ESTABLISHED:

- Hospital based multicentric, national registry studied the common medical retinal diseases such as Diabetic retinopathy, Age related macular degeneration, choroidal neovascular membranes, retinal vein occlusions which are treatable with Anti –VEGF.
- Registry: Network sites have enrolled ~ 11,000 patients of Diabetic retinopathy, Branch retinal vein occlusion and Central retinal vein occlusion, age-related macular degeneration, and chronic eye diseases registries across all sites.

IMPACT:

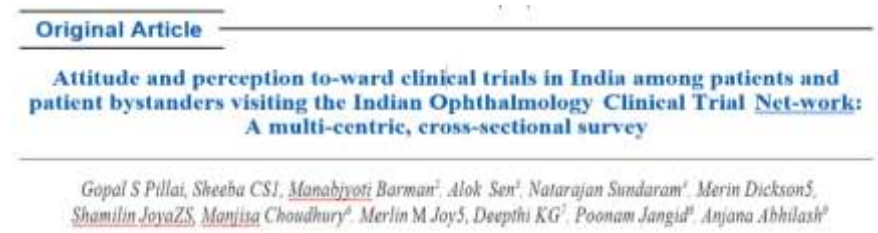
- Four International Publications on-
  - Knowledge and perception of health-care professionals on clinical trials in India: A pan-Indian cross-sectional survey.
  - Indian Ophthalmology Clinical Trial Network (IOCTN): A Pan-India Ophthalmology Clinical Trials Network for clinical research - Capacity building and early learnings
- Clinical Trials
  - 12 clinical trials have been initiated at CTN site sponsored by various pharmaceutical companies, where 02 clinical trials and 02 investigator-initiated studies in network mode.
  - The site Sri Sankara Deva Nethralaya Guwahati was inexperienced in clinical trial conduct before this project.

Signed MoU for network mode trials with:

- Fortea
- Syneos Health

OUTREACH ACTIVITIES:

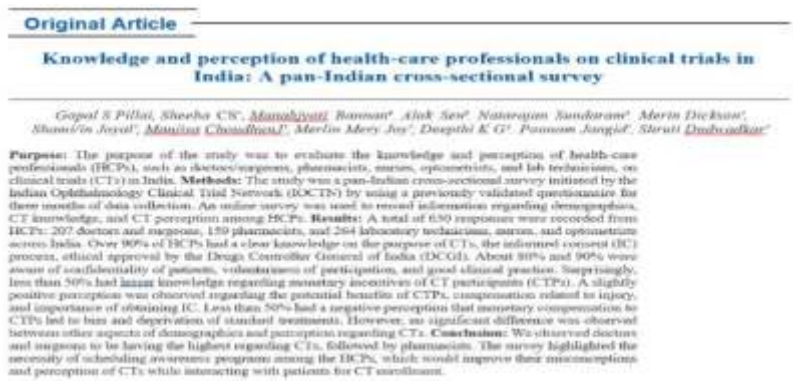
PUBLICATIONS:



Original Article

Attitude and perception to-ward clinical trials in India among patients and patient bystanders visiting the Indian Ophthalmology Clinical Trial Net-work: A multi-centric, cross-sectional survey

Gopal S Pillai, Sheeba CS1, Manabjyoti Barman2, Alok Sen2, Natarajan Sundaram2, Merin Dickson5, Shamilin JoyaZS, Manjisa Choudhury6, Merlin M Joy5, Deepthi KG7, Poonam Jangid8, Anjana Abhilash9



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Knowledge and perception of health-care professionals on clinical trials in India: A pan-Indian cross-sectional survey

Gopal S Pillai, Sheeba CS1, Manabjyoti Barman2, Alok Sen2, Natarajan Sundaram2, Merin Dickson3, Shamilin Joyal, Manjisa Choudhury5, Merlin Mery Joy1, Deepthi K G1, Poonam Jangid6, Shruti Deshpande7

Impact Created by Clinical Trial Networks

Key Highlights

Disease Epidemiology Data (Dengue, COVID, Chikungunya)	21 Multicentric Disease Registries >90,000 patient data	14 new Clinical Trial Units established
GCP, GCLP, GDP Trained Manpower	Access to >800 k healthy population for vaccine studies	E-Data Management Platforms
GIS Mapped DHS Sites across the country	Access to Urban, Semi-urban, Rural and Tribal Populations	10 publications from the networks

IMPACT SUMMARY

Ecosystem Strengthening

4x — Increase in assay expertise for product development

9x — Increase in preclinical product evaluation capacities

51.3 Cr — Consolidated Revenue Generated by shared facilities (in INR)

2x — Increase in clinical trial capacity

https://www.birac.nic.in/nbm/cms/page/facilities
https://www.birac.nic.in/nbm/cms/page/clinical-trial-network

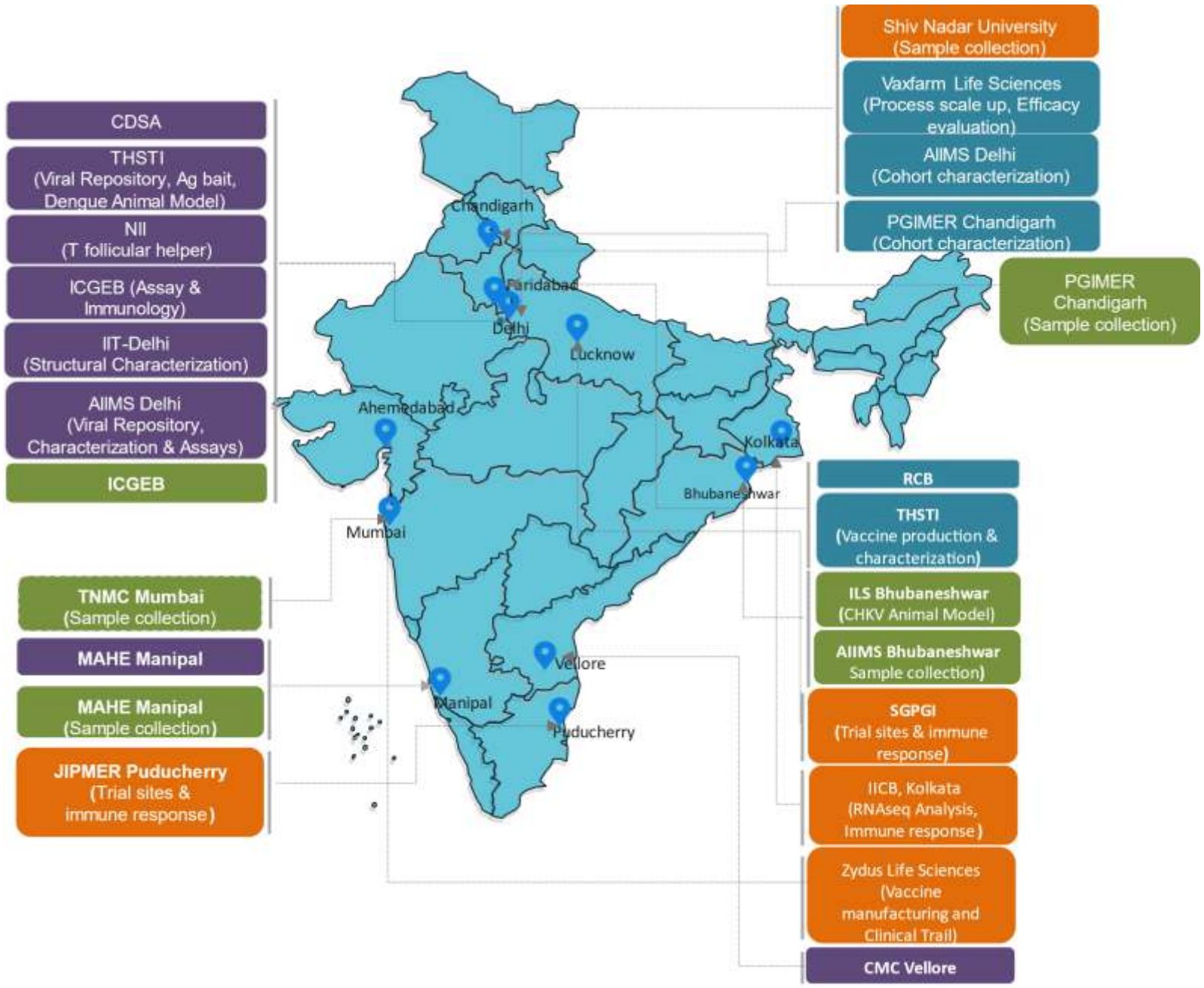
Ecosystem Strengthening ROLE OF NBM

Gap Mapping & Prioritization	**Facilities prioritized** • Detailed landscaping exercise done by NBM and IAVI. This followed meetings with advisory groups to identify kind of shared facilities required in the country and formulate the RFP contents and outreach activities to industry and academia
Funding	• Facilities funded for capacity strengthening, regulatory accreditations, manpower training. • Facilities funded, for acquiring advanced high-end equipment. • Facilities were funded, covering essential operational recurring costs. • NBM supported investment for high-risk infrastructure and instrumentation specifically for facilities
Scientific Mentorship	• Project Management and Advisory teams for shared facilities. • Technical support by TAG, SAG and PMUs.
Building Collabs. & Partnerships	• Fostered collaboration for novel biotherapeutics • Strengthen collaboration between academic technical capabilities and industrial manufacturing capacity • Cost-effective testing services for academia, startups, and manufacturers. • Collaborative assay development Enhanced capability and infrastructure for GLP assays in country • Provided referrals to other grantees for facility utilization
Facilitating Trainings	• Trained personnel at CT site on GXP • Supported skill development for lab personnel for regulatory compliant testing. • Increased skilled personnel availability, provided trainings to new ones, and the coexistence of both GCLP and BSL within a single facility.
Engaging Consultants	• Engagement of CDSA for strengthening, monitoring, and training sites • Engagement of IAVI and Sathguru for Knowledge Management support

Synergizing Science

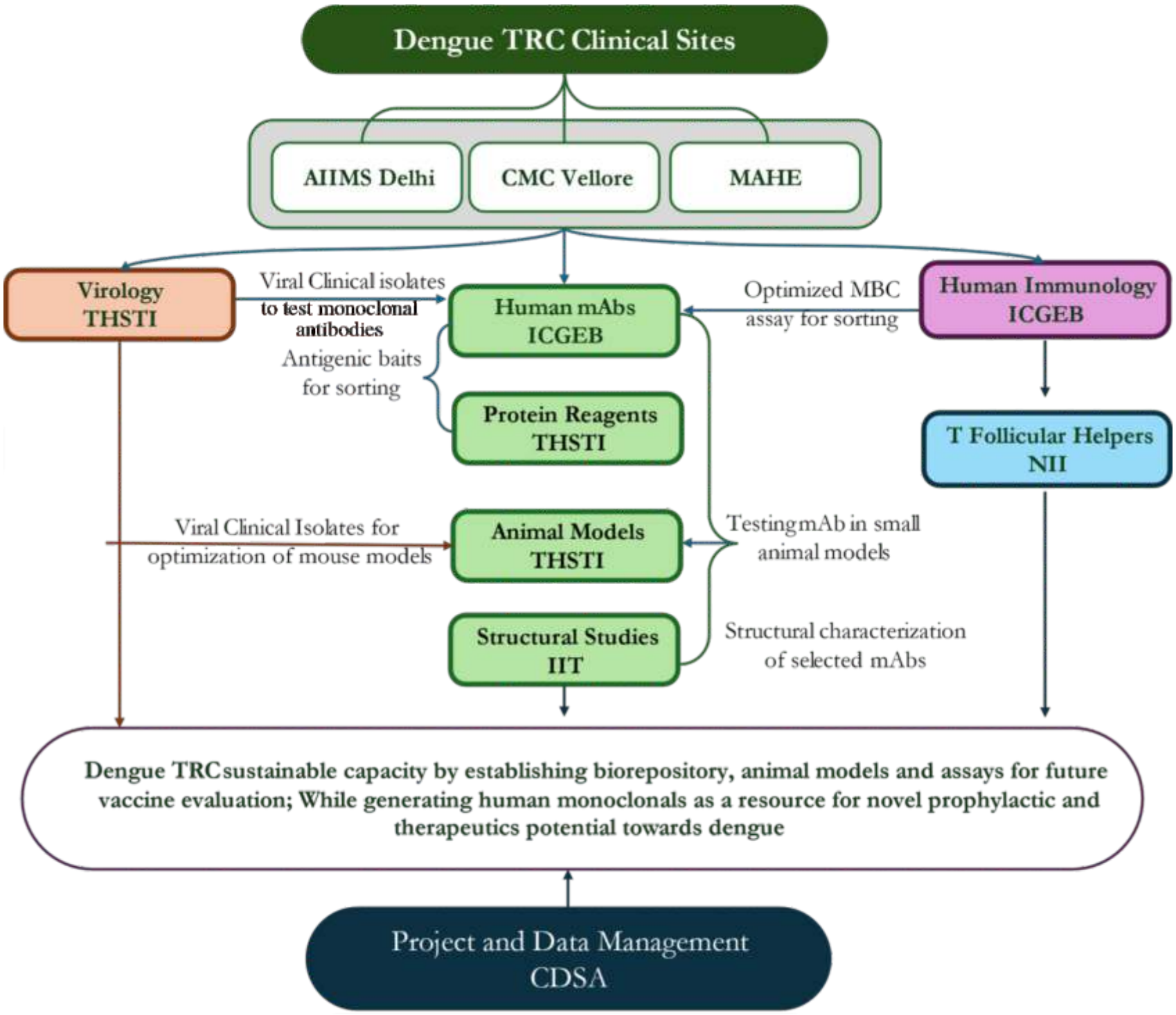
Establishing Translation Research Consortia for Enhanced Discovery

Translational Research Consortia (TRC)



HEV TRC-THSTI	HEV TRC-JIPMER	Dengue TRC	Chikungunya TRC
Clinical Trials	*Cohort Creation*	*Biorepository*	*Neutralizing assays*
Immunology	*Scale up*	*Translational Research*	*Serum Bank*
Neutralization Assays	*Clinical trails*	*Animal Assays*	*Biorepository*
		Immunology	*Animal Models*

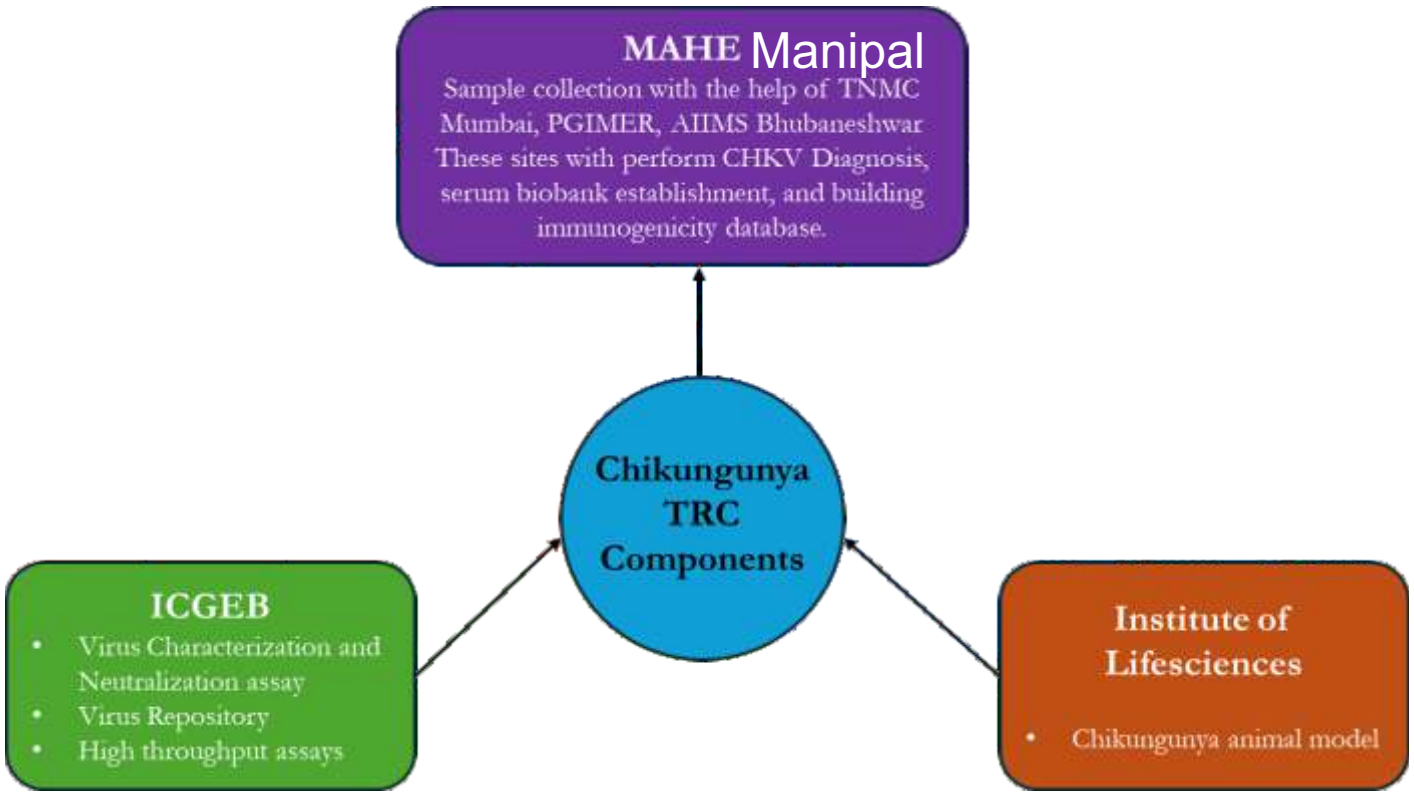
Translational Research Consortium
Dengue TRC



Translational Research Consortium
Dengue TRC

Need	• 50 Million dengue infections and ~500,000 hospitalizations, annually in India • Lack of sites with well studied disease epidemiology for conduct of community-based clinical trials for vaccine in country (NBM supported novel vaccine development for dengue) • Lack of capacity for Prophylactic and Therapeutic intervention development for Dengue
NBM Intervention	• Funding support to build unique interdisciplinary, complementary and synergistic expertise to tackle dengue. • Build TRC of 8 partners insitutes
Capacity Established	• Developed AG129 mouse model (Type I/II Interferon receptor deficient)- available for usage • Established Serum Biobanks with sera of 100+ exposed dengue patients. • Developed Dengue virus repository of 74 Indian clinical viral isolates with genome sequencing completed. • Reposited the isolates sequencing data resource to NCBI. • Isolated Human monoclonal antibodies against dengue viruses.
Capacity Utilized	• 3 collaborative projects, 2 MoU signed for antiviral drug and mRNA vaccine efficacy study so far

Translational Research Consortium
Chikungunya TRC



GRANTEE's VOICE

"The collaborative effort under the NBM's translational research consortium yielded significant achievements. The collaborative nature of the project, where different sites and disciplines converged to establish a robust research platform immensely supported project's outcomes, such as the clinical samples, biological insights, and animal models. This resource is anticipated to contribute not only to chikungunya research but also to broader advancements in the field of virology and vaccine development. The positive impact of NBM's coordination and monitoring efforts was acknowledged, underscoring the importance of sustained support for such research initiatives."

Translational Research Consortium
Chikungunya TRC

Need

- No existing vaccine against Chikungunya, globally
- CHIKV infection causes extremely painful arthralgia with burden of 45.26 DALYs per million
- Study of the pathogenesis of CHIKV hampered due to lack of animal model capacity in country.

NBM Intervention

- Supported with the aim to deliver a unique, interdisciplinary and synergistic expertise to tackle Chikungunya
- Chikungunya TRC is comprised of 5 institutes-ICGEB, New Delhi, TNMC, MAHE, ILS & PGIMER
- A dedicated software database to track Sample flow across sites in TRCs.
- Establishment of serum and virus culture repositories to ensure accessibility to researchers in country

Capacity Established

- Established CHIKV infectious clone based micro-neutralization assay
- Chikungunya acute and chronic model developed in C57BL/6 mice (4-6 weeks old).
- Established Serum Bio Bank with 3000+ aliquots deposited
- Established Virus Repository of 24+ CHIKN viral isolates completed with Characterization and WGS
- Developed a collection of 185 sera samples (paired acute and convalescent) along with isolated viruses from infected individuals

Capacity Utilized

- mAb isolation at ICGEB and animal facilities at THSTI were quickly leveraged for supporting COVID-19 studies during the pandemic.
- More than 13 collaborations established for animal model usage (7 of which are Academic collaborations)

Translational Research Consortium
Hepatitis E

Need

Hepatitis E virus [HEV] is the most common cause of enterically-transmitted viral hepatitis worldwide. Currently, there is only one licensed vaccine globally viz. Hecolinfrom Innovaxin China and is not available in India.

Need of Clinical trial , Immunologocal evaluation capacity, and neutralization potential of the antibodies using an in vitromodel.

NBM Intervention

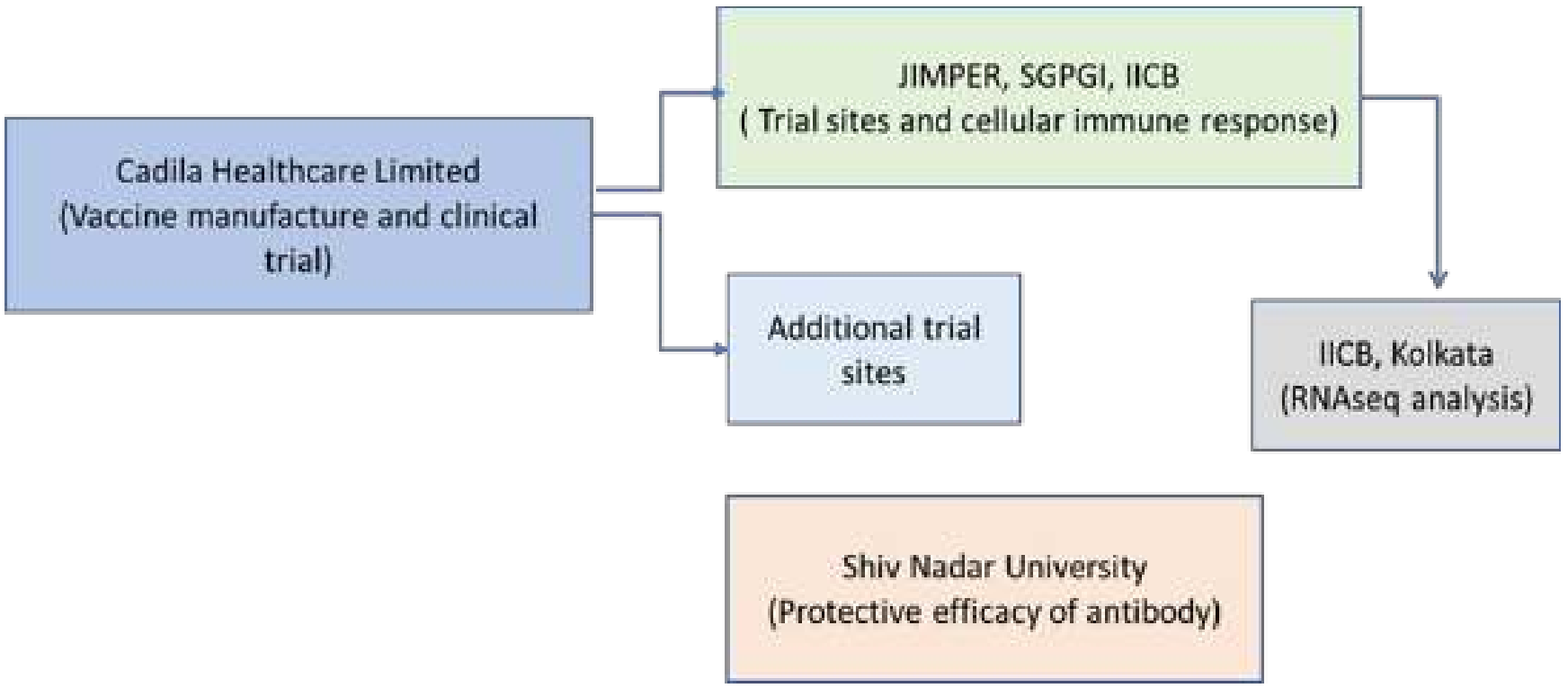
Supported HEV-JIPMER consortia, a collaboration between industry (Cadila) and academic partners led by JIPMER to carry out human clinical trial of a recombinant subunit candidate developed by

Fostered industry (Cadila)and academia collaboration for Phase II/ III clinical development of candidate vaccine in India

Towards the same, enabled partnership among SGPGI, Lucknow

- IICB, Kolkata
- Zydus Life science, Mumbai
- JIPMER, Puducherry
- Shiv Nadar University, Delhi

Capacity Utilized



Current Status

Phase II/ III clinical trials of candidate vaccine in India is ongoing

Empowering Pandemic Response

NBM's Strategic Efforts to Support COVID-19 Interventions

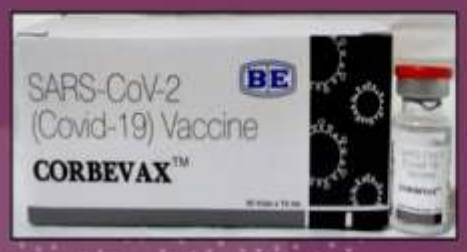
ZyCOV-D Covid Vaccine World's First and India's indigenously developed DNA Vaccine Emergency Use authorization (EUA) received in age groups 12years and above

Zydus DNA vaccine candidate against SARS-CoV-2, ZyCoV-D is the world's first and India's indigenously developed Plasmid DNA vaccine to be administered in humans. This vaccine candidate is comprised of a DNA plasmid Vector carrying S gene of 2019-nCoV spike-S protein.

Salient Features:

- **Plug and play technology:** The Plasmid DNA platform also allows generating new constructs quickly to deal with mutations in the virus, such as those already occurring.
- **Administration:** Two Dose/ Three dose intradermal vaccine: applied using The PharmaJet® needle free system, Tropis®, lead to a significant reduction in any kind of side effects
- **Storage:** 2-8 C
- **Ease of manufacturing** with minimal biosafety requirements (BSL-1)
- **Current Capacity:** 100-120 million doses annually
- Rapid large scale production feasibility
- Preclinical and Clinical Trial Data published in peer reviewed international journals

Corbevax™ COVID Vaccine Emergency Use authorization (EUA) received in age groups 05 years and above India's first heterologous booster vaccine for Covid



Biological E Limited's CorbevaxTM vaccine against COVID-19 is based on the antigen derived from the Receptor Binding Domain (RBD) of the Spike (S) Protein of SARS -CoV-2 surface. This COVD-19 vaccine is based on classical vaccine technology of a protein antigen, RBD, adsorbed to adjuvant Alum (Alhydrogel or AH), in combination with another approved adjuvant CpG 1018

Salient Features:

- Administration: Two Dose intramuscular vaccine
- Storage: 2-8 C
- Ease of manufacturing
- Current Capacity: 80-100 million doses annually
- Rapid large scale production feasibility, can be scaled to ~1 billion doses
- Total no. of doses sold in India: 98.52 Mn doses to GOI & 59,400 doses to private hospitals across India.
- Preclinical and Clinical Trial Data published in peer reviewed international journals
- Global Market: Approved in Botswana. Under review in many international markets

Covid Therapeutics and Platforms

Covid Therapeutics and Platforms Supported
Pegylated Interferon alpha-2b, 'Virafin' Phase 2 clinical trial supported by NBM For treatment of moderate COVID 19 infectionsinfection in adults

- Total Sales so far-13195 units
- Maximum likely patient exposure-10000
- Included in 3 state protocols, supplied to 4 states, 6 states actively considering including in protocol
- Availability in 214hospitals across the country.

zydus
Dedicated To Life

virchow
BIOTECH PRIVATE LIMITED

- Immunotherapy of COVID-19-infected patients using therapeutic antibodies from human plasma
- Studies byVirchow Biotech have demonstrated that it can improve the efficiency of patients' clinical parameters

Covid Diagnostic Kits in Market

Huwel LiveSciences Pvt Ltd

Huwel Lifesciences produced and marketed 200 lakhs Covid detection kits, 12 lakh units of Molecular Transport Medium (MTM) and 24 lakh nucleic acid extraction kits for sample preparation

Yaathum Biotech Pvt Ltd

An indigenous real-time RT-PCR based molecular diagnostic test to detect the SARS-CoV-2 virus; the virus that causes COVID-19 in upper and lower respiratory specimens. The assay is designed for the detection of nucleic acid from SARS-CoV-2 in 2 hours and at a fraction of the current cost of testing. It comprises three primer sets and 3 probes that target 3 regions in genomic RNA of SARS-CoV-2 and primer and probe set for RNAse-P internal positive control.

Mylab Discovery solutions Pvt Ltd

First Indigenous kit for diagnosis of COVID-19 developed by Mylab a BIRAC supported start up in Pune, produced nearly one lakh kits per week

Ubio Biotechnology Systems Pvt Ltd

Antibody detection kit by Ubio sold over 1 lakh tests. The two commercialized. products are SENSIT COVID IgG/IgM Kit and SENSIT COVID Antigen Kit.

Denovo Biolabs Pvt Ltd

Denovo Biolabs Pvt Ltd. has developed an indigenous, cost effective, robust, and rapid LFA POCT

Andhra Pradesh MedTech Zone (AMTZ)

AMTZ has manufactured 13 Crores RT-PCR tests, 4 Crores Covid-ELISA tests, 1.25 Crores Viral Transport Medium, 3000 units IR Thermometers, 11,000 units Ventilators.

Capacities Established by NBM Enabled Accelerated Development of COVID-19 Vaccines in India

The pre-empted efforts through the National Biopharma Mission Program initiated in 2018, enabled the of key resources and facilities that were swiftly updated and leveraged for COVID-19 vaccines in country. These were:

National Centre for Immunogenicity Testing at IRSHA, Pune

The laboratory, leveraging on the capacities established through NBM, established the capability to conduct neutralization assays that were leveraged by at least 2 COVID vaccines (GEMCOVID by Gennova and CORBEVAX by Biological E)

IgG Assays at Dr Dang's Lab

The Central Labs established for Serology and Biochemistry at Dr. Dang's lab through the DRIVEN Network were leveraged for IgG assays for multiple vaccines including Corbevax by Biological E.

Clinical Trial Sites

Of 11 sites through the DRIVEN network and 7 sites through the CHOORD (Consortia of Hospitals in the areas of Oncology, Ophthalmology, Rheumatology and Diabetology), 7 sites were leveraged for conduct of clinical trials of COVID-19 vaccine.

Immunoassays and animal facility at THSTI

THSTI was funded through the Translation Research Consortia for development of animal models and immunoassays. THSTI's animal facility and immunoassay (IgG, MSD multiplex, PRNT, CMI) capabilities were leveraged by Biological E and other manufacturers for development of COVID-19 vaccines.

Transforming Talent

Innovative Approaches to Skill Development

Trainings Outputs

43
trainings
Conducted

>7000
participants
trained including

3039
female
participants

33 GXP (GCP, GCLP)

06 regulatory compliance

04 bioethics

09
training under
Product Development

06
webinars on
Environment & Safety

Sero-Surveillance Trainings **01**

Establishment of DDESS sites **01**

AFI study protocol **01**

03
training for
Tech-transfer & Commercialization

Trainings on 'Good Clinical Practice' (GCP), 'Good Clinical Lab Practice' (GCLP) and 'Bioethics' were held in collaboration with CDSA

A series of webinars conducted for promoting Clinical Research Ethics capacity in India

A series of webinars on 'Environment, Health and Safety' to sensitize & create awareness about environment management and sustainability.

Trainings

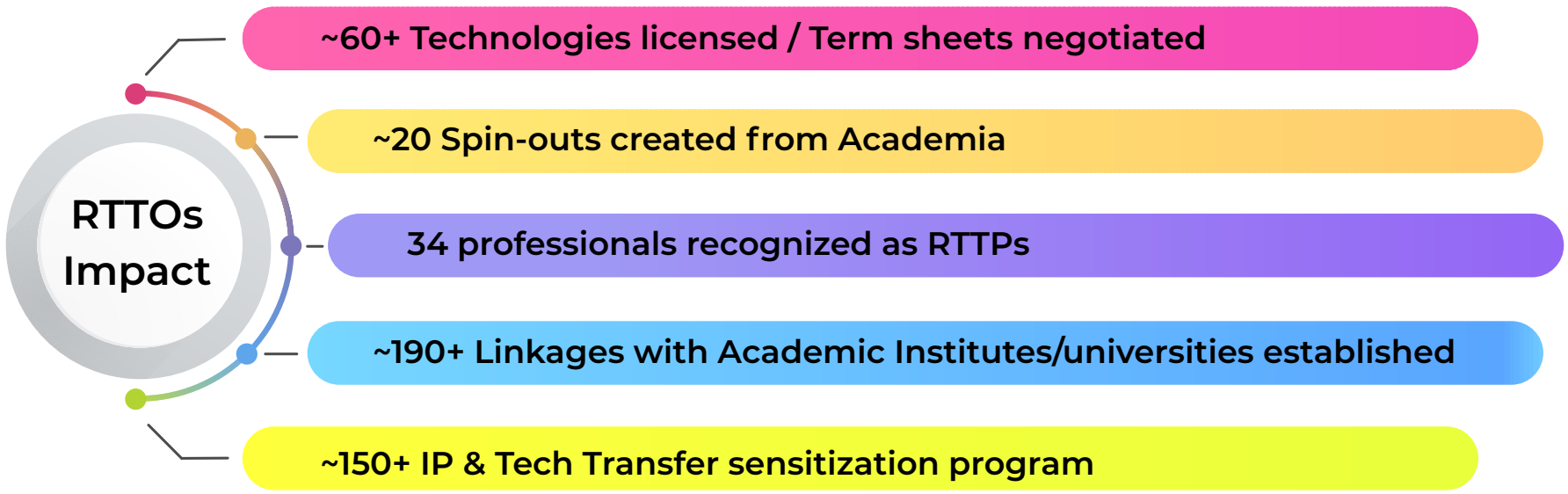
The Mission supports training and workshops as per its mandate. Workshops in the areas of clinical research, regulatory compliances, technology transfer, biopharmaceuticals and medical devices have been majorly supported. As on date, about 6968 participants have been trained under different trainings and workshops under the National Biopharma Mission including 3207 female participants.

Catalyzing Growth

Technology Transfer Offices

First and Largest National level Network of **Technology Transfer Offices**

Innovation ecosystem has gained momentum in India which is evidenced by the surge in patent filing over the last decade. Among the patent filers, teaching universities have been evolving as patent creators with a large number of filings coming from public institutional ecosystem. With such increasing patent filings from research institutions, there has also been a growing focus on technology transfer and commercialization. However, there is limited capacity in the country to forge such collaborations within public and private organizations and there is a critical need for enhancing capacity in the country of such professionals and institutions to enhance awareness in the domain of IP, tech transfer, licensing and commercialization activities that can bolster the translational research ecosystem in the country.



The National Biopharma Mission (NBM) established 7 Regional Technology Transfer Offices (RTTOs) to facilitate research translation and public-private partnerships by:

- Building internal and institutional capacity through training, immersion programs, and global connectivity.
- Facilitating partnerships between public and private institutions to commercialize novel technologies for market expansion at appropriate values.

These RTTOs service over 1310 academic, research institutions, and incubators. Tailored to each territory's unique ecosystem, they address specific needs based on economic development stages and regional needs

First and Largest National level Network of **Technology Transfer Offices**

These 7 RTTOs strive to build a strong foundation by strengthening the Biopharma ecosystem created by NBM. The TTOs are envisioned to create an impact in technology transfer ecosystem in the country by focusing on building blocks. The foundational pillars of the technology transfer ecosystem encompass four key building blocks as indicated below:

- Building Institutional and Professional Capacities by enhancing expertise within institutions and by training professionals for technology transfer.
- Forging Partnerships and Network Development highlights the critical role of collaboration in successful technology transfer, fostering connections between technology providers and absorbers.
- Commercialization of Technology centers on the seamless transition of innovations from research to the market, involving active participation in patenting and licensing.
- Strengthening Industry Connects prioritizing by bridging the gaps between academia and industry, fostering connections and initiatives to align technology transfer with industry needs.

Together, these building blocks form a comprehensive framework for effective technology transfer, driving innovation from conception to real-world application.

₹ 1.75 crore
Highest transaction amount for Global Exclusive license for a formulation and delivery method of screening of oral cancer and identification of the biopsy site in four milestones with royalties.

300+
Hours of mentorship with 100+ hours of international mentorship and 200 hrs of domestic mentorship.

8
Industrial problem statements for which technologies scouted.

450+
IP Clinics, IP awareness and IP sensitization workshops.

34
Technology Transfer professionals accrediated as RTTPs

25+
Technologies licensed to industry.

The advancements mentioned highlight India's progress in innovation, particularly seen in increased patent filings and commercialization by universities. However, there's a need for better collaboration between public and private sectors. National-level initiatives like RTTOs have facilitated technology transfer, translational research, and public-private partnerships. Capacity-building efforts have equipped professionals to navigate technology transfer complexities, leading to socio-economic impacts. Partnerships between institutions have boosted technology commercialization and created a supportive environment for startups. RTTOs have also promoted gender inclusivity, with around 63% of professionals being women. Overall, these efforts have strengthened India's technology transfer ecosystem, drove socio-economic impact and supporting startups while prioritizing gender inclusivity.

Glimpses of technology transferred

MoU between TIMed and HuT Labs, Amrita Vishwa Vidyapeetam

TTO FITT Innovation-Technology Transfer Office (i-TTO), FITT facilitated transfer of three frugal and socially impactful technologies successfully on September 14, 2023 to M/s Rudray Industries, a Nashik based start-up.

License Agreement transactions facilitated by KIIT-TBI TTO
Technology: Synthesis of toluidine blue o & a kit for mucosal application (QuickBlue)
Application: Early detection of oral potentially malignant & malignant disorder

BCIL : Technology: A novel process for the production of the anti-diabetic sugar, D-allulose, by using a D-allulose 3-epimerase of Bacillus sp. Origin - technology was transferred to M/S Kothari Sugar and Chemicals Ltd (KSCL) on April 04, 2024.

Environment, Health and Safety Awareness

Innovating and Streamlining Environmental Risk Management

National Biopharma Mission or the Innovate in India for Inclusiveness (i3) Project facilitates innovation in biopharmaceutical products and medical devices that address public health priorities in India. The Project has significant achievements to date including intellectual property (IP) registrations, technologies licensed for manufacturing or commercialization, products that address public health priorities, technology transfer offices established, and many companies using the shared facilities supported by the project. During the COVID pandemic, the project had a major impact on vaccine development, supporting the development of two COVID-19 vaccines, which received emergency authorization in 2021. These include Cadila Healthcare, the world's first DNA vaccine, and Corbevax, a protein subunit vaccine.

An Environmental, occupational health, and safety management framework guide the environmental management under the Project. It provides a simplified checklist based Environmental actions that ensures National / State Regulatory requirements are adhered in mission supported activities. To effectively screen and manage risks and impacts, the project prepares and uses Environmental Health Risk Management Plans (EHRMPs). As the Project numbers progressed from 9 to 140 plus calls, the pointers in EHRMP moved from 10 to 60 for reporting, including any impacts on the surrounding Environment, management of various types of wastes (including hazardous, biomedical, e-waste and liquid wastes) from the project facilities, Occupational and Community Health and Safety, regulatory compliance, emergency preparedness, and COVID 19 / other pandemic risks among others to follow the project Environmental Monitoring Framework (EMF).

Figure A: Pillars of Environmental, Health & Safety Management in the Project

The need to submit an EHRMP along with the proposals from potential grantees is made part of the Request for Proposals (RFP) enabling an early screening of the risks and impacts. This is further updated by the Grantees based on the guidance from subject experts / consultants of BIRAC. Updated EHRMPs are disclosed on the website of BIRAC/NBM. Environmental management capacities at Project level include an in-house Environmental expert and support consultants at National level and Environmental Nodal Officers at the Grantees. A robust framework is established for regular site visits, feedback, and follow-ups with the grantees, and to receive quarterly updates from the grantees on actions taken for fulfilling any pending environmental compliance-related and safeguards management issues. Training on EMF elements is enabled through a separate module as part of the activities of skill developments, in addition to regular dedicated onsite training to each Grantee on their Environmental Safeguard requirements and risk management during the expert's site visits. Grantees are guided on regulations and accreditation requirements at National level which helped in aligning them with the regulations and good practices' while the planning, agreement & reporting through EHRMPs helped them bring good practices to implementation.

Filled up Environmental Health Risk Management Plan (EHRMP) of PRMP submitted by eligible applicants reviewed by Legal cell, Environment and safety officer

Applicants address and refines the EHRMP as per review comments and changes

Refined EHRMP will be reviewed by Legal cell, Environment and safety officer than included in the GLA — Display of EHRMP in the website

Once GLA executed the NBM Environment consultant visits the site and reviews the EHRMP is in line with the site conditions

NMB Environment consultant gives observations in site visit report specific to the Grant/Grantee & the Grantee takes action to update EHRMP & implement Corrective Actions

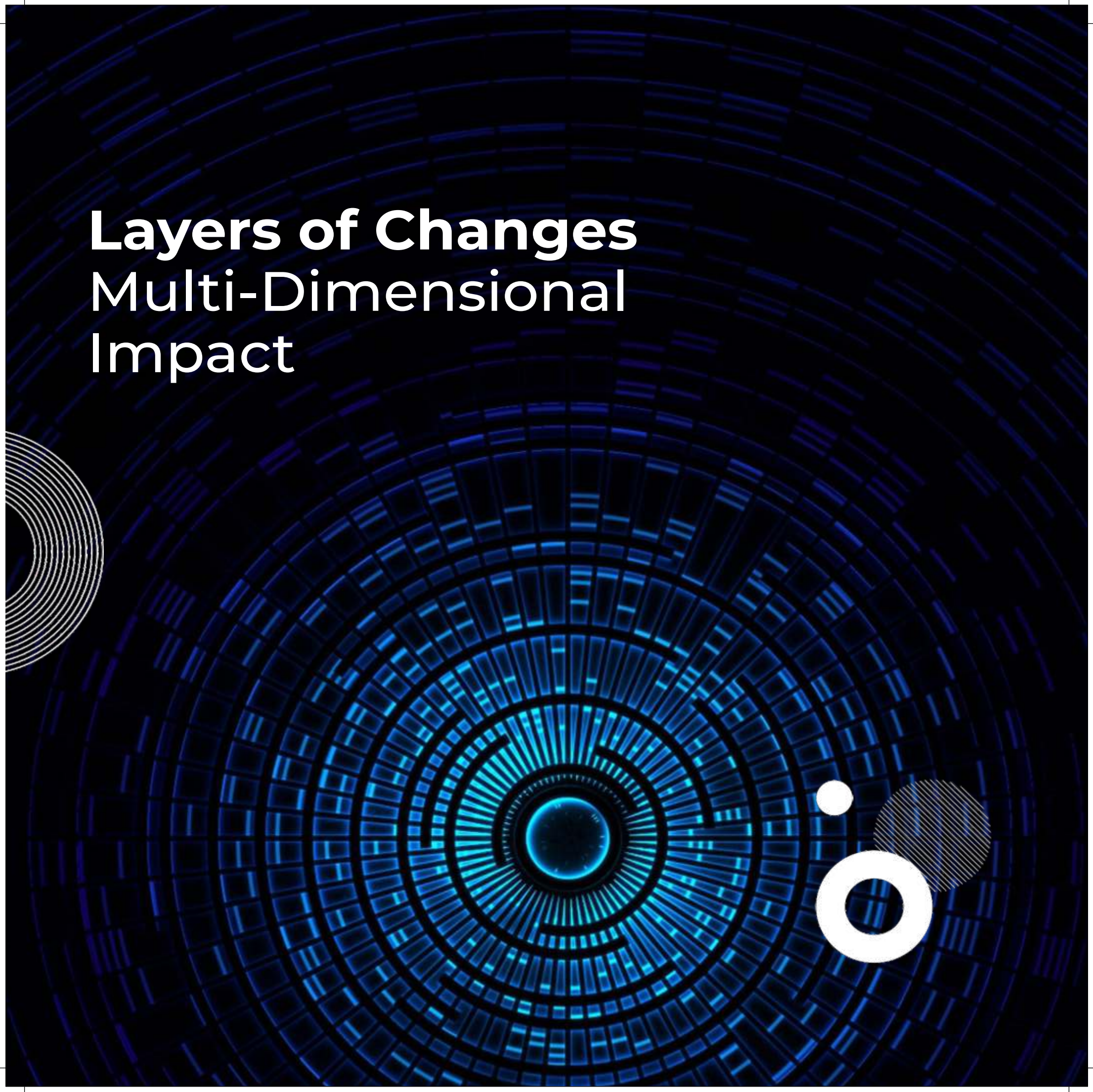
Figure B: EHRMP internalization

The EHRMP adoption process focuses more on hands on support & capacity building of the Grantees - especially of the small entities, contrary to documentation heavy / preparation focused environmental management attempts. Results include State of Art facilities for environmental management at the Grantees, aligned with National Regulations on Waste Management, Good International Laboratory Practices including Health and Safety and Pollution Management.

Figure C: Environmental Management Strategy

Figure D: Process focused heavily on hands on support & capacity building

Layers of Changes
Multi-Dimensional Impact



Outputs till date

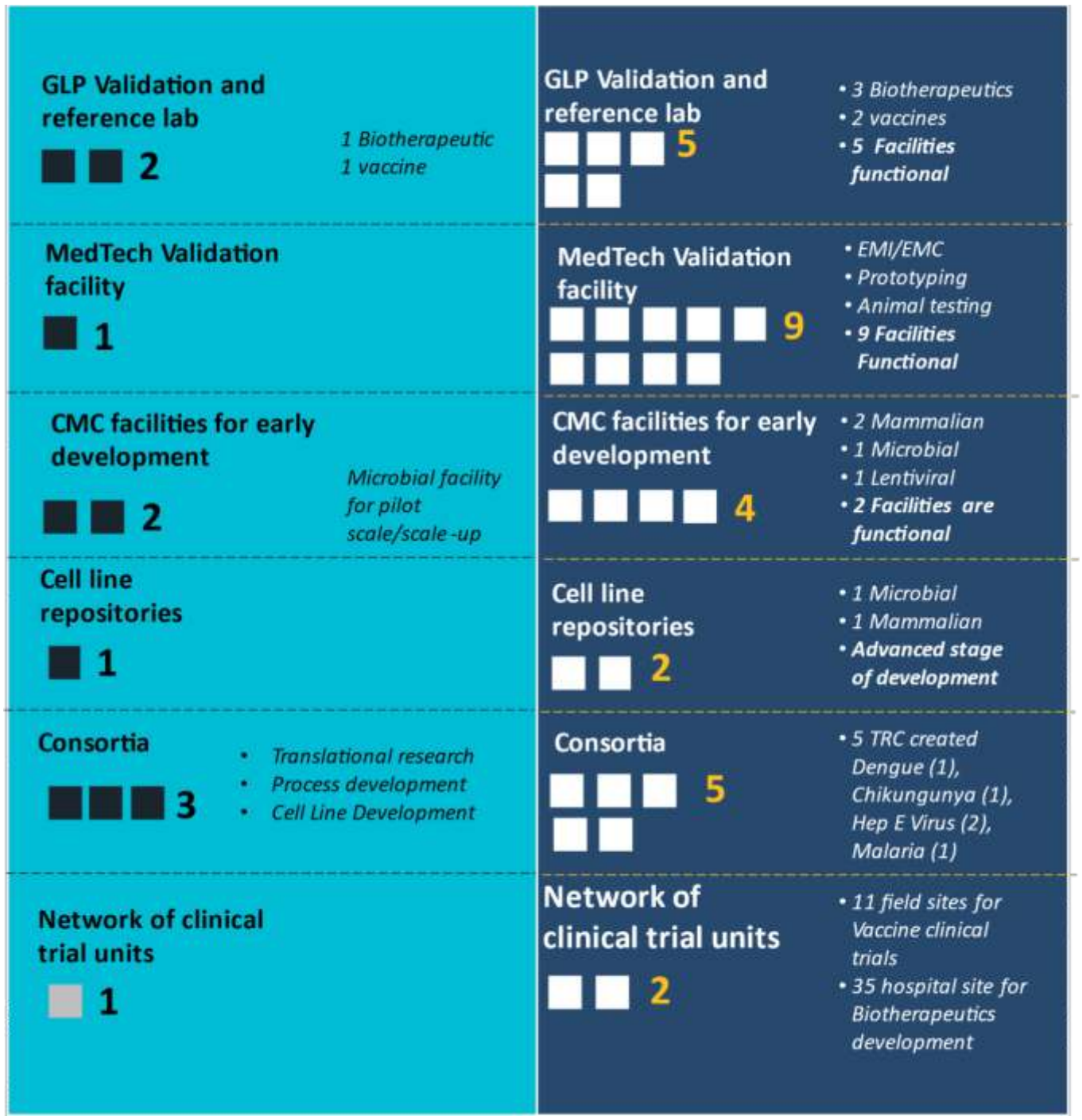
Product Development

Projects Supported by NBM. (Product development)

Each box indicates one product supported in each section. Products supported are categorized based on products type (vaccine, biotherapeutics and medical devices) and stage of development (PoC to clinical, late-stage manufacturing)

Outputs till date

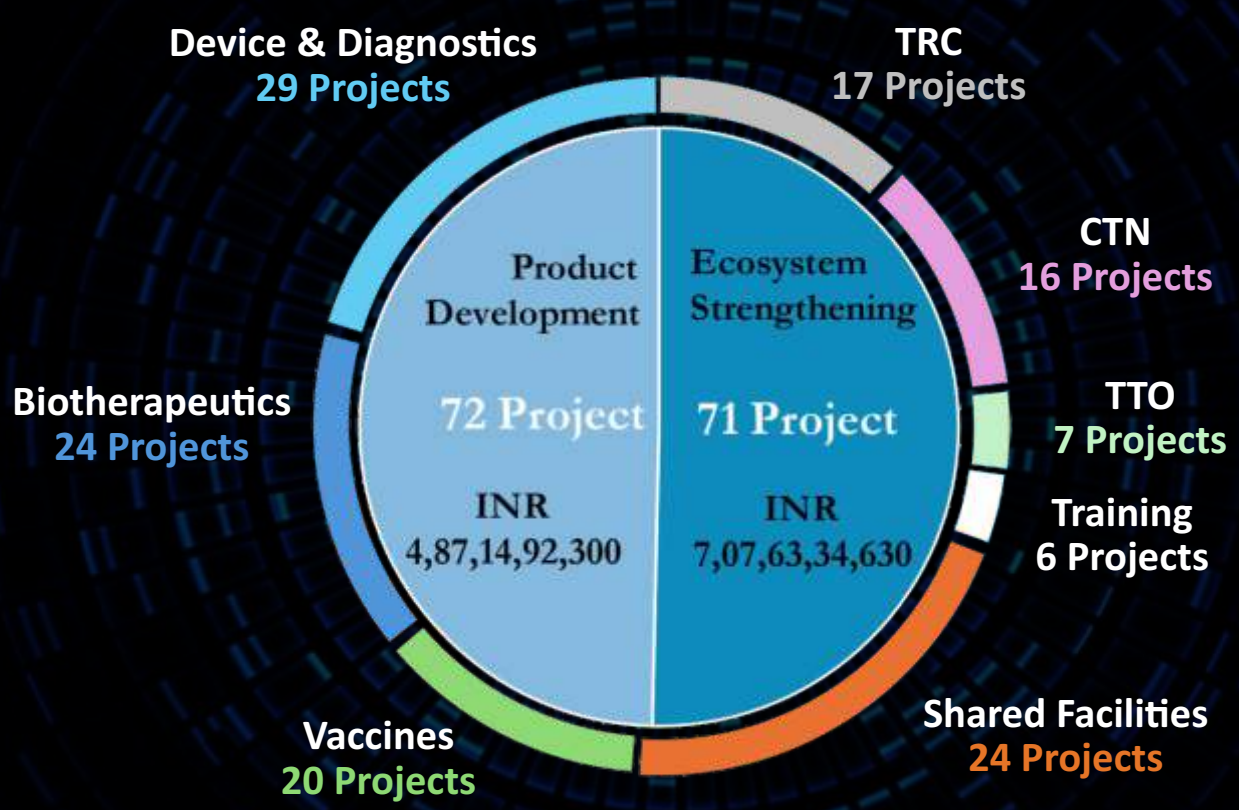
Ecosystem Strengthening



Projects Supported by NBM. (Ecosystem Strengthening)
Each box indicates one project supported in each section.

143 Projects

~₹13,00,00,00,000 Invested



19 Products Commercialized	22 state-of-the-art facilities Supported	>7,000 People Trained
33 IPs Generated	1065 human capital supported	55 Peer-Reviewed papers published

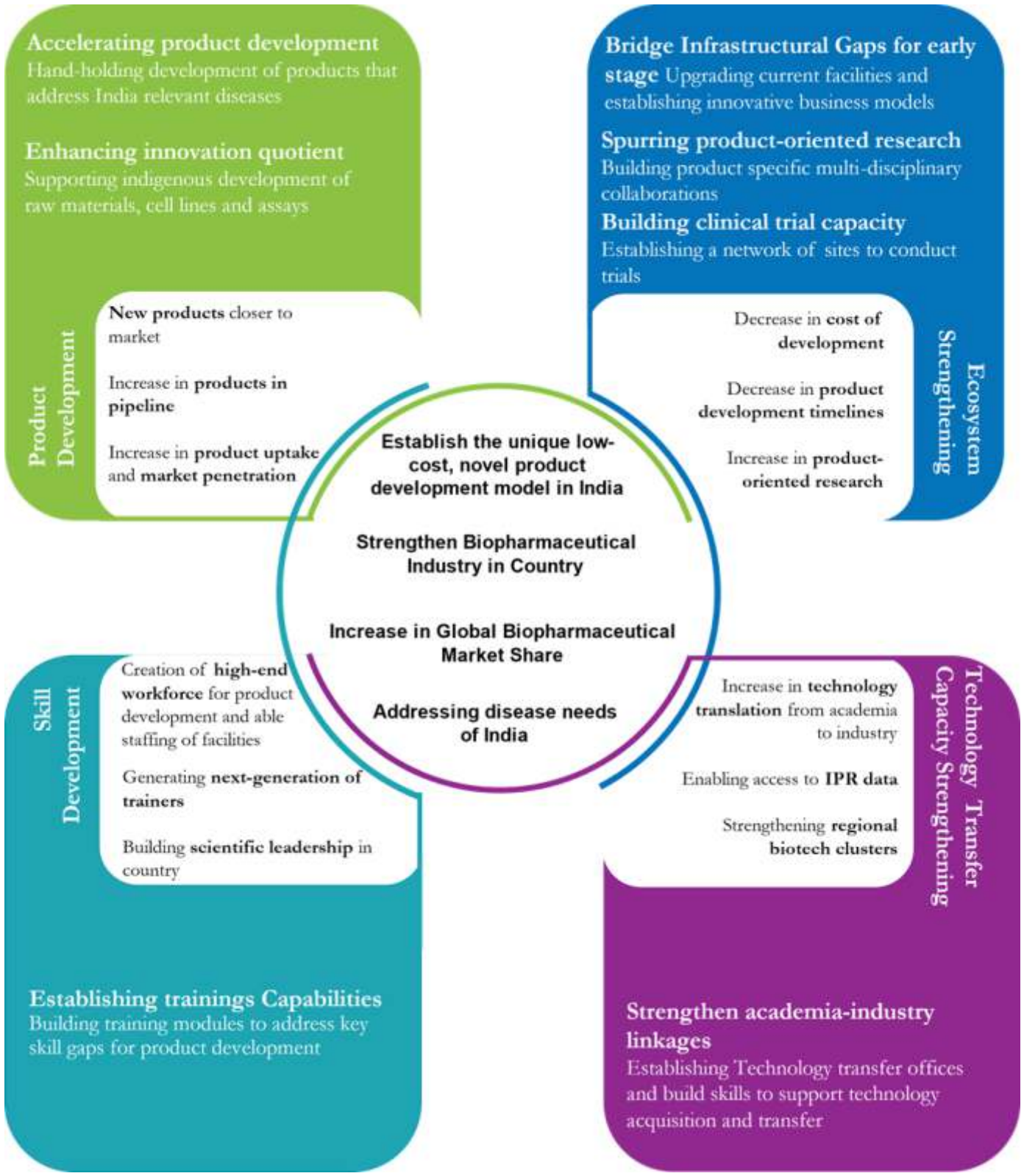
235 **Millions of people benefitting from strengthened capacity to prevent, detect, and respond to health emergencies**

From current intervention

Approach Adopted for Assessment

Grantees were surveyed through questionnaires and one-on-one interviews to evaluate the total resources mobilized and the number of people benefiting from product development and capacity strengthening.

Multi-Layered Impact Created



Acknowledgements

ACKNOWLEDGEMENT

NBM would like to extend heartfelt gratitude to the people behind the Mission's achievements through this section of the IMPACT BOOK.

Foremost, we acknowledge the current leadership of DBT, Dr Rajesh S Gokhale, Secretary DBT & Chairperson BIRAC, Dr Alka Sharma, Scientist H and Advisor DBT, former MD BIRAC and Dr Jyoti Logani, Scientist F and nodal officer NBM. We thank them for their critical inputs. engaging support motivating our team at various occasions where it was needed.

We also express deep gratitude to the visionary leaders late Professor MK Bhan, Professor Padmanaban, Prof. K. Vijay Raghavan, Dr Renu Swarup, who conceptualized this Mission to boost the growth curve for domestic biopharma in India. Their guidance and mentorship in the initial stages was pivotal to lay the foundation of the Mission.

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5.	Secretary, Department of Pharmaceuticals, M/o Commerce and IP, New Delhi
6.	Director General, ICMR and Secretary, Department of Health Research, M/o Health & FW
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8.	Chairman, Technical Advisory Group (TAG), NBM
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11.	Managing Director, BIRAC
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NBM Team with World Bank members
Mr. Andres Garcia, Dr. Dinesh Nair, Dr. Ayesha

NBM Team with BIRAC Colleagues and senior management BIRAC - 2023
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Dr. Raj Shirumalla, Dr. Jitendra Kumar (MD BIRAC), Dr. Jyoti Lugani (DBT),
Dr. Subhra Chakrabarti, Dr Lalitha Balakrishnan

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Clinical trial site monitoring team - CDSA

Sathguru Management Consultant team - for TTO

Abbreviation

Abbreviations

Abbreviations	Full form
ADC	Antibody-drug conjugate
AIIMS	All India Institute of Medical Sciences
ALL	Acute lymphocytic leukaemia
AST	Antimicrobial Susceptibility Testing
BIRAC	Biotechnology Research Assistance Council (BIRAC),
BSL	Bio Safety Level
CAGR	Compound annual growth rate
CAR-T	Chimeric antigen receptor-T cell therapy
CDSA	Clinical Development Services Agency
CDSCO	Central drug standard control organization
cGMP	Clinical good manufacturing practices
CHIKV	Chikungunya virus
CHOORD	Consortia of Hospitals in the areas of Oncology, Ophthalmology, Rheumatology and Diabetology
CMC	Christian medical college
CoGs	Cost of goods
CRO	Clinical research organization
CT	Clinical Trial
CTN	Clinical trial network
D & D	Devices and Diagnostics
DBT	Department of Biotechnology
DCVM	Developing Countries Vaccine Manufacturers
DNA	Deoxyribonucleic acid
DHSS	Demographic Health Surveillance Systems
DNA	Deoxyribose nucleic acid
DSS	Demographic Surveillance Systems
ELISA	Enzyme-linked immunosorbent assay
EMA	European Medicines Agency
EUA	Emergency use authorization
FACS	Fluorescence-activated cell sorting
FDA	Food and Drug Administration
GAVI	Global Alliance for Vaccine Initiative

GCLP	Good Clinical Lab Practices
GCP	Good Clinical Practices
GDP	Good Documentation Practices
GDP	Gross Domestic Product
GLP	Good Laboratory Practices
GPP	Good Participatory Practices
GxPs	Good Practices (Abbreviation)
HPV	Human papillomavirus
IAP	Indian Academy of Paediatrics
ICGEB	International Centre for Genetic Engineering and Biotechnology
ICH	The International Conference on Harmonization
IICB	Indian Institute of Chemical Biology
IIL	Indian immunological limited
IIT	Indian Institute of Technology
IPR	Intellectual Property Rights
ISO	International Standard Organization
JIPMER	Jawaharlal Institute of Postgraduate Medical Education & Research
KIMS	Krishna Institute of Medical Sciences
KL	Kilo Litre
KOLs	Key opinion leader
L	Litre
LA	Live attenuated
LMIC	Low- and middle-income countries
MA	Market authorization
mAb	Monoclonal Antibody
MAHE	Manipal Academy of Higher Education
MAMC	Maulana Azad Medical College
MOPA	Multiplex Opsonophagocytic Assay
MoU	Memorandum of Understanding
MRI	Magnetic Resonance Imaging
MTA	Material Transfer Agreement
MTM	Molecular Transport Medium
NABL	National Accreditation Board for Testing and Calibration Laboratories
NBM	National Biopharma Mission
NCBI	National Centre for Biotechnology Information

NII	National Institute of Immunology
NSCLC	Non-Small Cell Lung Cancer
NTAGI	The National Technical Advisory Group on Immunization
OECD	Organization for Economic Cooperation and Development
QA/QC	Quality Assurance/Quality Check
PCV	Pneumococcal Virus
PDL-1	Programmed Death-Ligand 1
PoC	Proof of Concept
PMU	Project Management Unit
R&D	Research and Development
RFP	Request For Proposals
rHSA	Recombinant Human Serum Albumin
RNA	Ribonucleic Acid
RT-PCR	Reverse Transcription Polymerase Chain Reaction
RTTO	Regional Technology Transfer Offices
SAG	Scientific Advisory Group
SARS-COV	Severe Acute Respiratory Syndrome
SGPGI	Sanjay Gandhi Post Graduate Institute of Medical Sciences
SJRI	St. John's Research Institute
SOMAARTH	Seamless Online Management and Administration of Academic Resources for Teachers and Higher Education Institutions
SMEs	Small and Medium Enterprises
SOP	Standard Operating Procedure
TAG	Technical Advisory Group
THSTI	Translational Health Science and Technology Institute
TMC	TATA Memorial Centre
TRC	Translational Research Consortia
TRC	Translational Research Consortia
µ	Micron
VEGF	Vascular Endothelial Growth Factor
VLP	Virus-Like Particles
WGS	Whole Genome Sequencing
WHO	World Health Organization

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